

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
2 May 2002 (02.05.2002)

PCT

(10) International Publication Number  
**WO 02/34305 A2**

(51) International Patent Classification<sup>7</sup>: **A61L 15/34**,  
15/42

(21) International Application Number: PCT/US01/32013

(22) International Filing Date: 11 October 2001 (11.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
09/694,052 20 October 2000 (20.10.2000) US

(71) Applicant: **KIMBERLY-CLARK WORLDWIDE, INC.** [US/US]; 401 N. Lake Street, Neenah, WI 54956 (US).

(72) Inventors: **KRZYSIK, Duane, Gerard**; 1112 E. Melrose Avenue, Appleton, WI 54911 (US). **OTTS, David**,

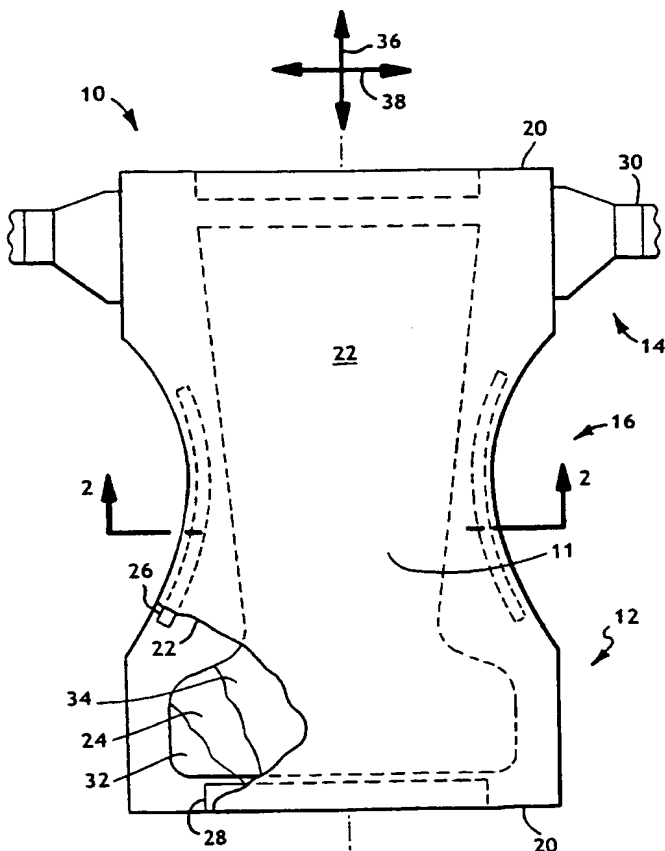
**Roland**; 809 N. Kensington Drive, Appleton, WI 54915 (US). **LANGE, Beth, Anne**; 415 S. Olde Oneida Street, #319, Appleton, WI 54911 (US). **NELSON, Brenda, Marie**; 3124 S. Huckleberry Lane, Appleton, WI 54915 (US). **BROCK, Earl, David**; 645 Highview Lane, Kimberly, WI 54136 (US). **TATE, Martha, Lillian**; 7390 Twin Branch Road, Atlanta, GA 30328 (US).

(74) Agents: **DUDKOWSKI, Alyssa, A.** et al.; Kimberly-Clark Worldwide, Inc., 401 N. Lake Street, Neenah, WI 54956 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: ABSORBENT ARTICLES ENHANCING SKIN BARRIER FUNCTION



(57) Abstract: The present invention relates to compositions and absorbent articles including compositions for protecting and enhancing the barrier function of the skin. The compositions can be applied to the bodyfacing surfaces of absorbent articles so that the compositions come into contact with the skin. The compositions of the invention have improved stability on the bodyfacing surfaces after processing. The compositions of the invention provide several benefits including prevention and alleviation of skin irritations associated with the use of absorbent articles. The compositions can include natural fats, natural oils, sterols or sterol derivatives, emollients, solidifying agents and viscosity enhancers.

WO 02/34305 A2

BEST AVAILABLE COPY



(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU,

ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

**Published:**

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

## **Absorbent Articles Enhancing Skin Barrier Function**

### **Field of the Invention**

The present invention relates to the inclusion of lipid-enriched, hydrophobic compositions with improved stability on the bodyfacing materials of disposable absorbent articles, such as diapers, training pants, adult incontinence products, underpants, feminine care products, nursing pads, wound dressings and similar articles having absorbent capacity. The present invention also relates to improving skin health by protecting and enhancing the barrier function of the skin through delivery of hydrophobic compositions from the bodyfacing materials of disposable absorbent articles to the skin. Prior to delivery to the skin, the compositions are stable on the bodyfacing materials. The compositions of the invention can also provide benefit to the barrier function of the skin when they are incorporated into other skin-contacting materials such as tissues, wet wipes and cosmetic cleansing or buffing pads.

15

### **Background of the Invention**

The stratum corneum is the outer-most layer of the skin and is responsible for regulating skin water levels and functioning as a barrier against chemicals and other stress agents found in the environment. The complex arrangement of lipids in the intercellular space of the stratum corneum is responsible for the establishment of normal barrier function. Multi-layered structures of cholesterol, ceramides and fatty acids, as well as some other minor lipids, provide the major barrier to the transport of substances into or through the skin. The overall structure of the stratum corneum acts as the frontline barrier to the skin. The link between skin barrier function and skin health is apparent from the skin inflammation caused by lipid extraction from the skin. That is, when skin barrier function is impaired, the other layers of the skin can be injured and have a response to that injury in the form of inflammation.

In the area of skin health, it is known to apply lipid-containing compositions to the skin in order to enhance the barrier function of the stratum corneum. This approach is disclosed in U.S. Patent No. 5,643,899 issued to Elias et al. on July 1, 1997. For some time, those of skill in the art have believed that it is necessary to apply all three of the lipid

components of the stratum corneum (cholesterol, ceramides and fatty acids) to the skin in order to replenish and repair the skin and in order to not affect the normal repair processes of the skin. In particular, ceramides are believed to be very important. In fact, the art teaches that if fewer than all three of the components are used in a skin composition, the composition could actually compromise or delay repair of the barrier.

5 In U.S. patent application Serial No. 09/379,928 filed August 24, 1999, various compositions for improving skin health are described, including compositions suitable for use in conjunction with absorbent articles. The compositions in patent application Serial No. 09/379,928 were found to provide benefits for skin health. The compositions were described as containing a variety of potential components and, in some forms, the compositions included natural fats and oils, sterols and sterol derivatives, humectants and surfactants. These compositions have been found to improve skin health even though they do not necessarily include any ceramides. Efficacy without ceramides was unexpected. Though the exact mechanism of functionality was not known, one hypothesis was that an emulsion of the lipid components (natural fats/oils and sterols/sterol derivatives) was formed in the humectant component (through the use of a surfactant). In some of the embodiments that were described, the humectant was glycerin. Incorporation of such an emulsion into an ointment formulation was predicted to be more easily absorbed or taken up by the skin. The ointment formulation, which could include petrolatum, would form an occlusive film on the skin, thereby trapping water between the skin and the occlusive film. The trapped water was predicted to facilitate uptake of the emulsion and, therefore, the natural fats/oils and sterols, by the skin. Therefore, the humectant and surfactant components of the compositions were perceived to be facilitating the transfer of the lipid components to the skin.

25 Therefore, benefits and improvements to skin health have been observed when compositions containing the lipids naturally present in the stratum corneum are applied to the skin. Though the exact mechanisms are not known, one hypothesis is that the lipids being applied with the compositions are replenishing lipids that have been lost from the stratum corneum as a result of physical or biological insults. Another hypothesis is that the lipids being applied with the compositions are providing additional lipids to the stratum corneum resulting in better protection against insults. The stratum corneum of the skin is constantly exposed to physical and biological insults that could have a negative effect on barrier function.

35 Absorbent articles such as diapers, training pants, incontinence products and feminine care products are worn such that they are in direct contact with the skin of the wearer. An unavoidable consequence of the use of absorbent articles is that the skin is

exposed more directly to various physical and biological insults. Consequently, the barrier function of the skin covered by the absorbent article is put at risk. In order to provide disposability, absorbent articles are primarily constructed of nonwoven materials. Even though nonwoven materials are engineered to have soft hand and drape, they rub against the skin and there is friction. Such friction constitutes one form of physical insult to the skin barrier. Friction against the skin barrier also occurs with the use of absorbent tissues and wipes. Absorbent tissue and wipe products are frequently used for cleansing the skin areas covered by absorbent articles. Absorbent tissue and wipe products are necessary for removing biological waste materials from the skin.

In addition to these physical insults, skin covered by absorbent articles is also frequently exposed to biological insults. Biological fluids, such as urine, feces, vaginal secretions and nasal secretions, may contain a variety of components that can damage the skin barrier. Examples of these components include proteases, lipases and bile acids. Once the skin barrier is compromised, these components, in addition to other constituents of biological fluids, can initiate or exacerbate inflammation of the skin.

Diaper dermatitis is a genre of skin conditions that, in large part, originate from impaired skin barrier function. Impairment of the skin barrier can result from a variety of factors, including: increased skin hydration due to the occlusion of the skin caused by diapers, enzymatic skin damage due to fecal and urinary enzymes, and physical damage caused by friction against the diaper surface and repeated cleaning of the skin with absorbent tissues or wet wipes.

Excessive hydration of the skin also has a negative effect on the skin barrier. The hydration level of diapered skin, for example, may reach between five to ten times that of undiapered skin. Frequent contact of diapered skin with urine may also contribute to increased skin hydration. Increased skin hydration disrupts skin lipid organization in the stratum corneum. This disruption may increase the permeability of the skin to irritants from feces and urine, thus increasing the risk of skin inflammation.

Disposable absorbent articles such as diapers, training pants, adult incontinence products, absorbent under pants, feminine care products and nursing pads have been used to absorb body fluids and leave the skin dry. Disposable absorbent articles of this type generally include a liquid impermeable backsheet member, an absorbent core or assembly, and a liquid permeable body facing or liner material. The body facing or liner material comes into contact with the wearer's skin. While the body facing material is made of a soft, compliant material, the material rubs against the skin during use and may not leave the skin completely dry and free of the bodily fluids, such as solid or semi-solid waste, the absorbent article is trying to absorb. During frequent insults of bodily fluids and

frequent use of disposable absorbent articles, the skin can become irritated and appear red and be sore to the touch.

5 Creams, lotions or ointments can be used to provide an artificial hydrophobic barrier on the skin and to treat skin conditions such as diaper rash. Application of these types of products to the skin is often messy and inconvenient. Often, these products are not used prophylactically and are only used when signs of diaper rash are visible.

10 Diaper liners and other bodyfacing materials may be treated with emollients, such as petrolatum, that can be transferred to the skin through normal diapering practices. Once transferred to the skin, diaper liner formulations may provide an artificial barrier against feces and urine. These formulations may require high concentrations of petrolatum to ensure sufficient transfer to the skin to provide a benefit. High concentrations of petrolatum can be messy, greasy to the touch, and may impair the fluid handling properties of an absorbent article, such as a diaper. The slow penetration of petrolatum into the skin can lead to smearing of the agent over the skin and onto clothes and other materials.

15 Formulations, such as those containing petrolatum, are applied to the bodyfacing materials of absorbent articles during manufacture. In order to process and apply the formulations to the bodyfacing materials, the formulations need to be in a semi-solid or fluid state. However, in order to have stability on the bodyfacing material after manufacture, the formulations need to be semi-solid or solid across a wide range of shipping and storage temperatures. Not all of the presently known formulations are sufficiently stable on the bodyfacing materials. Consequently, such formulations may transfer off of the bodyfacing material prematurely or the formulations may migrate away from the skin-facing surfaces of the materials.

25 Thus, what is needed is a topically effective composition delivered from a bodyside or bodyfacing material of an absorbent article that protects, maintains, recovers or otherwise benefits skin barrier function against physical damage and irritants in biological fluids. It would also be desirable to provide a topical composition delivered from a bodyside material of an absorbent article that absorbs into the skin, is non-greasy and cosmetically acceptable to the consumer. Additionally, it would be desirable to provide a topical composition having improved stability on the bodyside material of an absorbent article. Further, it would be desirable to provide a topical composition delivered from a bodyside material of an absorbent article that does not impair the waste containment functions of the absorbent article.

35

### **Summary of the Invention**

In response to the difficulties and problems discussed above, compositions and the use of those compositions on absorbent articles for improving the barrier function of the skin have been discovered. The compositions of the invention provide several benefits associated with barrier function including protecting, strengthening, restoring and repairing the skin barrier. While the compositions of the inventions can have a variety of applications, the compositions are particularly beneficial when used in conjunction with absorbent articles such as diapers, incontinence garments, feminine care products, training pants, diaper pants, nursing pads and wound dressings. Additionally, the compositions of the invention could also provide benefits when used in conjunction with tissue, pre-moistened wipe products and cosmetic cleansing and buffing pads. A further benefit of the compositions of the invention is that the compositions show improved stability during processing and application to an article. The purposes and advantages of the present invention will be set forth in and apparent from the description that follows, as well as will be learned by practice of the invention. Additional advantages of the invention will be realized and attained by the compositions and articles particularly pointed out in the written description and claims hereof, as well as from the appended drawings.

In one aspect, the present invention relates to an absorbent article that includes an outer cover, a bodyside liner, an absorbent body and a composition. The bodyside liner is typically liquid permeable and defines a bodyfacing surface. The bodyside liner is connected in a generally superposed relation to the outer cover. The absorbent body is located between the bodyside liner and the outer cover. The composition is on a portion or the entire bodyfacing surface of the bodyside liner. The composition can be generally solid, semi-solid or liquid. The composition may be in a variety of forms, including, but not limited to, emulsions, lotions, creams, ointments, salves, suspensions, gels and the like. The composition can be applied to the bodyside liner using a variety of techniques including foam application, spraying, slot coating and printing. The present invention also encompasses technology that would permit integration of the composition directly with fibers or other materials used to form the bodyside liner. The compositions can be applied to the bodyfacing surface in amounts of from about 0.1 grams per meter squared ( $\text{g/m}^2$ ) to about 30  $\text{g/m}^2$ .

The compositions of the invention could also be applied to or be present on other skin contacting surfaces of absorbent articles such as the waist and leg elastics and the containment flaps. The compositions include from about 0.1 to about 95 percent by weight of natural fats or natural oils. More specifically, the compositions can include from

about 5 to about 75 percent by weight of natural fats or natural oils. Desirably, the compositions of the invention include from about 10 to about 50 percent by weight of natural fats, natural oils or mixtures of both. Natural fats and oils include fats, oils, essential oils, fatty acids, fatty alcohols, phospholipids and mixtures of these compounds.

- 5 The natural fats and oils can be similar to the lipids that are present in healthy skin in order to mimic the naturally present lipids. Synthetic or synthetically modified fats and oils could potentially also be used if they functioned in the same manner as their natural counterparts. Examples of fats and oils include Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, 10 Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lanolin, Lanolin Alcohol, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Behenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, 15 Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

- The compositions also include sterols, sterol derivatives or mixtures of both in an amount of from about 0.1 to about 10 percent by weight. Sterols and sterol derivatives include compounds such as  $\beta$ -sterols with a tail on the 17 position and no polar groups, 20 such as cholesterol,  $C_{10}$ - $C_{30}$  cholesterol/lanosterol esters, tall oil sterols, soy sterols, sterol esters and mixtures of these compounds. More specifically, the compositions include from about 0.5 to about 5 percent by weight of sterols, sterol derivatives or mixtures of both. Even more specifically, the compositions include from about 0.8 to about 1 percent by weight of the sterol compounds. Examples of suitable sterol compounds include 25 cholesterol, sitosterol, stigmasterol, and ergosterol, as well as,  $C_{10}$ - $C_{30}$  cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanosterol, soy sterol, avocado sterols, 30 "AVOCADIN" (available from Croda Ltd. of Parsippany, New Jersey), sterol esters and mixtures thereof.

- The compositions of the invention further include from about 1 to about 95 percent by weight of one or more emollients. More specifically, the compositions include from about 20 to about 75 percent by weight of emollient(s). Even more specifically, the 35 compositions include from about 40 to about 60 percent by weight of emollient(s). Suitable emollients include petroleum based oils, petrolatum, vegetable oils, mineral oils,



alkyl dimethicones, alkyl methicones, alkyldimethicone copolyols, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin and its derivatives, fatty esters, glycerol esters and their derivatives, propylene glycol esters and their derivatives, alkoxylated carboxylic acids, alkoxylated alcohols, fatty alcohols and mixtures of such compounds.

5           The compositions of the invention also include from about 5 to about 95 percent by weight of one or more solidifying agents. More specifically, the compositions include from about 25 to about 75 percent by weight of solidifying agents. Even more specifically, the compositions include from about 30 to about 50 percent by weight of solidifying agents. A solidifying agent is a material capable of solidifying the composition so that the  
10 composition is solid at room temperature and has a penetration hardness of at least 5 mm. More specifically, the solidifying agent includes one or more materials that are capable of solidifying the natural fats/oils and emollient combination so as to have a penetration hardness of 5 to about 365 mm at 25°C. Further, the solidifying agent solidifies the fat/oil/emollient combination so that it has a melting point between 32°C and 100°C. One  
15 or more solidifying agents can be selected from alkyl siloxanes (with a melting point greater than 35°C), polymers, waxes (animal, vegetable or mineral), hydrogenated vegetable oils having a melting point of 35°C or greater and fatty acid esters having a melting point of 35°C or greater.

          Examples of suitable solidifying agents include, but are not limited to, the following  
20 compounds: alkyl silicones, alkyl trimethylsilanes, beeswax, C<sub>24</sub>-C<sub>28</sub> alkyl dimethicone, C<sub>30</sub> alkyl dimethicone, cetyl methicone, stearyl methicone, cetyl dimethicone, stearyl dimethicone, cerotyl dimethicone, candelilla wax, carnauba, cerasin, hydrogenated microcrystalline wax, jojoba wax, microcrystalline wax, lanolin wax, ozokerite, paraffin, cetyl esters, behenyl behenate, C<sub>20</sub>-C<sub>40</sub> alkyl behenate, C<sub>12</sub>-C<sub>15</sub> lactate, cetyl palmitate,  
25 stearyl palmitate, isosteryl behenate, lauryl behenate, stearyl benzoate, behenyl isostearate, cetyl myristate, cetyl octanoate, cetyl oleate, cetyl ricinoleate, cetyl stearate, decyl oleate, di-C<sub>12</sub>-C<sub>15</sub> alkyl fumerate, dibehenyl fumerate, myristyl lactate, myristyl lignocerate, myristyl myristate, myristyl stearate, lauryl stearate, octyldodecyl stearate, octyldodecyl stearyl stearate, oleyl arachidate, oleyl stearate, tridecyl behenate, tridecyl  
30 stearate, tridecyl stearyl stearate, pentaerythrityl tetrabehenate, pentaerythritylhydrogenated rosinatate, pentaerythrityl distearate, pentaerythrityl tetraabeite, pentaerythrityl tetracocoate, pentaerythrityl tetraperlargonate, pentaerythrityl tetrastearate, ethylene vinyl acetate, polyethylene, hydrogenated vegetable oil, hydrogenated squalene, hydrogenated coconut oil, hydrogenated jojoba oil, hydrogenated  
35 palm oil, hydrogenated palm kernel oil, hydrogenated olive oil, polyamides, metal stearates and other metal soaps, C<sub>30</sub>-C<sub>60</sub> fatty alcohols, C<sub>20+</sub> fatty amides, polypropylene,

polystyrene, polybutane, polybutylene terephthalate, polydipentane, polypropylene, zinc stearate and mixtures of such compounds.

In addition to the components already described, the compositions of the invention may further include from about 0.1 to about 25 percent by weight of one or more compounds acting as viscosity enhancers. More specifically, the compositions include from about 5 to about 20 percent by weight of one or more viscosity enhancers. Even more specifically, the compositions include from about 10 to about 15 percent by weight of viscosity enhancer(s). The viscosity enhancer increases the meltpoint viscosity of the compositions to have a high viscosity at the "hot box car" stability temperature of approximately 54.5°C. Having high viscosity at elevated temperatures prevents the compositions from migrating into or away from the materials to which they are applied. However, the viscosity enhancer component also provides a low viscosity (<200 centipoise) for the compositions at process temperatures. Typically, process temperatures are approximately 5°C above the melting point of the composition.

Examples of suitable viscosity enhancers include polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, polyethylene, silica, silica silylate, silica methyl silylate, colloidal silicone dioxide, alkyl hydroxy ethyl cellulose, other organically modified celluloses, PVP/decane copolymer, PVM/MA decadiene crosspolymer, PVP/eicosene copolymer, PVP/hexadecane copolymer and mixtures of these compounds.

In addition to one or more viscosity enhancers, the compositions of the invention may also include one or more rheology modifiers. Rheology modifiers are compounds that increase the viscosity of the compositions at lower temperatures as well as process temperatures. Rheology modifiers are also compounds that provide "structure" to the compositions to prevent settling out (separation) of insoluble and partially soluble components. By increasing the viscosity at process temperatures, the rheology modifiers will increase the viscosity above 200 centipoise. However, the rheology modifiers are thixotropic in behavior; therefore, their viscosity decreases as shear and pressure increases. Consequently, when the rheology modifiers are used in the compositions of the invention, they maintain the suspension of insoluble and partially soluble components. This capability can be particularly important if, during processing, the composition must be left stagnant in process lines and hoses. The rheology modifiers will maintain the suspension of the insoluble and partially soluble components for a period of time that depends on the viscosity of the composition and on the amount of rheology modifier present. The thixotropic behavior of the rheology modifiers causes their viscosity to drop when processing is resumed and the composition is no longer stagnant due to the application of pressure and shear forces. In addition to stabilizing the suspension of

insoluble and partially soluble components, the rheology modifiers of the invention also help to stabilize the compositions on the bodyfacing or other materials to which the compositions are applied. Examples of suitable rheology modifiers include silica, silica silylate, silica methyl silylate, quaternary starch compounds and mixtures thereof. Such  
5 rheology modifiers can help maintain the suspension of a partially soluble emollient, such as a siloxane, within the composition. The compositions of the invention can include from about 0.5 to about 5 percent by weight of one or more rheology modifiers.

The stability of the compositions of the invention can also be improved through the use of one or more alkyl silicones as one of the solidifying agents in the composition.  
10 Alkyl silicones have been found to facilitate the homogenous incorporation of some emollients, such as siloxanes, into the hydrocarbon-based compositions of the invention. The ability of alkyl silicones to stabilize siloxanes (silicones) was unexpected given the inherent incompatibility of siloxanes with oils such as may be used in the compositions of the invention. The inherently high molecular weights of alkyl silicones are believed to be a  
15 factor in their role as solidifying agents. Additionally, the alkyl silicones are believed to act as coupling agents for the siloxanes with the organic phase of the composition which may include fats/oils, waxes or petrolatum. The ability of alkyl silicones to couple the siloxane and organic phases of the composition is due to the alkyl functionality incorporated into the siloxane molecule. Thus, by possessing both silicone and alkyl functionalities in the  
20 same molecular structure, physically stable siloxane/hydrocarbon compositions can be achieved. The alkyl silicones are able to maintain the homogeneity of the siloxanes in the compositions even at higher temperatures, such as may be experienced during processing, where the absence of the alkyl silicone will result in severe phase separation of the siloxane from the composition. Typically, alkyl silicones having a high molecular  
25 weight ( $C_{12}$  or greater, or a high degree of alkyl substitution) are desirable for the compositions of the invention. Siloxanes having a high degree of polymerization are also desirable. The compositions of the invention can include from about 0.5 to about 30 percent by weight of one or more siloxanes, such as dimethicone. Additionally, the compositions of the invention can include from about 0.5 to about 30 percent by weight of  
30 one or more alkyl silicones.

As will be described later in further detail, the compositions of the invention have been shown to enhance the barrier function of the stratum corneum of the skin. The presence of the compositions of the invention on the skin, when the skin is subjected to physical and biological insults, has been shown to be beneficial. Though the exact  
35 mechanism(s) is not known, it is possible that the compositions of the invention provide a superior barrier that prevents the skin from uptaking moisture. Based on the hypothesis

that emulsions of lipid components (fats and oils/sterols) in a humectant facilitate the transfer of lipids to the skin, it was unexpected that compositions having no water soluble components could enhance the barrier function of the skin. Without water soluble components, it was believed that there would be no mechanism to facilitate transfer of the fats, oils and sterols to the skin.

In addition to the components already described, the compositions of the invention may also include active ingredients such as those ingredients that may be useful for treating skin irritations such as diaper rash. Examples of such active ingredients include allantoin and its derivatives, aluminum hydroxide gel, calamine, cocoa butter, cod liver oil, dimethicone, glycerin, kaolin and its derivatives, lanolin and its derivatives, mineral oil, petrolatum, shark liver oil, talc, topical starch, zinc acetate, zinc carbonate, zinc oxide and mixtures of these ingredients. Some of the ingredients listed as possible active ingredients for treating the skin can also be used as emollients.

In order to enhance or increase the function of the compositions of the invention, additional ingredients may be added. Examples of the classes of ingredients along with their functions include: antifoaming agents (reduce the tendency of foaming during processing); antimicrobial actives; antifungal actives; antiseptic actives; antioxidants (product integrity); antioxidants-cosmetic (reduce oxidation); astringents-cosmetic (induce a tightening or tingling sensation on skin); astringent-drug (a drug product that checks oozing, discharge, or bleeding when applied to skin or mucous membrane and works by coagulating protein); biological additives (enhance the performance or consumer appeal of the product); colorants (impart color to the product); deodorants (reduce or eliminate unpleasant odor and protect against the formation of malodor on body surfaces); other emollients (help to maintain the soft, smooth, and pliable appearance of the skin by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin's appearance); external analgesics (a topically applied drug that has a topical analgesic, anesthetic, or antipruritic effect by depressing cutaneous sensory receptors, or that has a topical counterirritant effect by stimulating cutaneous sensory receptors); film formers (to hold active ingredients on the skin by producing a continuous film on skin upon drying); fragrances (consumer appeal); silicones/organomodified silicones (protection, tissue water resistance, lubricity, tissue softness); oils (mineral, vegetable, and animal); natural moisturizing agents (NMF) and other skin moisturizing ingredients known in the art; opacifiers (reduce the clarity or transparent appearance of the product); powders (enhance lubricity, oil adsorption, provide skin protection, astringency, opacity, etc.); skin conditioning agents; solvents (liquids employed to dissolve components found useful in the cosmetics or drugs); and

surfactants (as cleansing agents, emulsifying agents, solubilizing agents, and suspending agents).

Ranges are used to describe the relative quantities of compounds in the compositions of the invention and ranges are used to describe the relative physical properties of the compositions of the invention. It is understood that the ranges are by way of illustration only and that one of skill in the art would recognize that the nature of the specific compositions dictates the levels to be applied to achieve the desired results. The levels of components are ascertainable by routine experimentation in view of the present disclosure.

The compositions of the invention typically have a melting point of from about 32°C to about 100°C. Melting behavior in this range provides compositions that are relatively immobile and localized on the bodyfacing surface of the bodyside liner of the absorbent article at room temperature. Though relatively immobile and localized at room temperature, the compositions are also readily transferable to the wearer of the article at body temperature through natural rubbing or friction during wearing and through adhesion of the composition to the skin of the wearer. The compositions also maintain their integrity and are not completely liquid at elevated temperatures such as may be experienced during storage. Stability in a solid state at elevated temperatures is made possible, in part, to the increase in viscosity provided by the viscosity enhancers. Desirably, the compositions of the invention are easily transferable to the skin by way of normal contact, including adhesion of the composition to the skin, wearer motion or body heat. Because the compositions are relatively immobilized on the bodyfacing surfaces of the articles, the quantities of the compositions necessary to provide the desired skin barrier benefits are reduced. In addition, special barrier or wrapping materials may not be necessary for the articles of the invention.

The compositions of the invention have viscosities that range from about 10 to about 10,000 centipoise as measured at a temperature of 60°C. At 55°C, the compositions have viscosities from about 200 centipoise to about 100,000 centipoise. The compositions may also have a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.

In addition to the articles and compositions already described, the present invention is also directed to absorbent articles that include an outer cover, a liquid permeable bodyside liner, an absorbent body and a composition on at least a portion of the bodyside liner. The bodyside liner defines a bodyfacing surface and the bodyside liner is connected in superposed relation to the outer cover. The absorbent body is located

between the bodyside liner and the outer cover. The composition is on at least a portion of the bodyfacing surface of the bodyside liner.

The composition can include from about 0.5 to about 75 percent by weight of natural fats or oils. The natural fats and oils may be selected from avocado oil, borage oil, sunflower oil, soybean oil, corn oil, cottonseed oil and mixtures of such fats and oils. The composition can also include from about 0.5 to about 5 percent by weight of sterols and sterol derivatives. The sterols and sterol derivatives may be selected from cholesterol, sitosterol, stigmasterol, tall oil sterol, soy sterol and mixtures of such sterols. Additionally, the composition can include from about 20 to about 75 percent by weight of one or more emollients. The emollients may be selected from petrolatum, silicone oils, dimethicone, lanolin and mixtures of such emollients. The composition can also include from about 25 to about 75 percent by weight of one or more solidifying agents. The solidifying agents may be selected from alkyl silicones, beeswax, C<sub>24</sub>-C<sub>28</sub> alkyl dimethicone, C<sub>30</sub> alkyl dimethicone, cetyl methicone, stearyl methicone, cetyl dimethicone, stearyl dimethicone, cerotyl dimethicone, candelilla wax, carnauba, cerasin, hydrogenated microcrystalline wax, jojoba wax, microcrystalline wax, lanolin wax, ozokerite, paraffin, cetyl esters and mixtures of such solidifying agents. The composition further includes from about 5 to about 20 percent by weight of one or more viscosity enhancers. The viscosity enhancers may be selected from ethylene/vinyl acetate copolymers, polyethylene, silica and mixtures of such viscosity enhancers. The composition may also include a rheology modifier for providing stability of insoluble and partially soluble components.

The articles with respect to this aspect of the invention may have compositions on at least a portion of the bodyfacing surface of the bodyside liner in which the compositions may have certain physical properties. For example, the compositions may have melting points of from about 32°C to about 100°C such that the compositions are relatively immobile on the bodyfacing surface at room temperature but are readily transferable to the skin at body temperature. The compositions may also have viscosities that range from about 10 to about 10,000 centipoise at a temperature of 60°C and a viscosity of from about 200 centipoise to about 100,000 centipoise at 55°C. Additionally, the compositions may have a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C. The compositions may be applied to at least a portion of the bodyfacing surface in an amount of from about 0.1 grams per meter squared (g/m<sup>2</sup>) to about 30 g/m<sup>2</sup>. Those of skill in the art will know how to modify the components and attributes of the compositions encompassed by the invention to achieve the desired skin barrier benefits based on the disclosure provided herein.

The present invention is further directed to a method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article. The method of the invention includes a step of heating a composition to a temperature above the melting point of the composition. The composition can have a melting point of from about 32°C to about 100°C. The composition can include a natural fat or oil, a sterol or sterol derivative, an emollient, a solidifying agent and a viscosity enhancer. The method further includes a step of applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article. The bodyfacing surface is that surface of the absorbent article that comes into contact with the skin of the wearer of the absorbent article. Other components of the absorbent article besides the bodyside liner may come into contact with the skin of the wearer. The composition can also be applied to those components including the waist elastics, the leg elastics, containment flaps and any other components coming into contact with the skin.

The composition can be applied to the bodyfacing surface using a variety of techniques including foam application, spraying, slot coating, printing or combinations of these application techniques. The method of the invention also includes a step of resolidifying the composition. The composition can be resolidified in a variety of ways including chilling, slow cooling, curing or a combination of these techniques. Further, the composition can have a penetration hardness of from about 5 to about 365 millimeters at 25°C after the step of resolidification.

In another embodiment, the present invention is directed to a composition. While the composition may have other useful functions, the composition generally provides a benefit to the function of the skin barrier. The composition can include from about 0.1 to about 95 percent by weight of one or more natural fats or oils, or the composition can include a mixture of one or more natural fats and oils. The composition can also include from about 0.1 to about 10 percent by weight of one or more sterols, sterol derivatives or mixtures of both sterols and sterol derivatives. An additional component of the composition of the invention can be from about 1 to about 95 percent by weight of one or more emollients. The emollient(s) can act as a lubricant to reduce abrasiveness and help to maintain a soft, smooth and pliable appearance to the skin. The composition can further include from about 5 to about 95 percent by weight of one or more solidifying agents. The solidifying agent(s) can function as solidifiers or stabilizers for the emollient(s) and natural fats/oils of the composition, provide a tackiness to the composition that improves transfer properties and act as an occlusive agent, moisturizer or barrier enhancer. The composition of the invention can also include from about 1 to about 25 percent by weight of one or more viscosity enhancers. The viscosity enhancer(s) can

modify the viscosity of the composition to improve the consistency of the composition for the purpose for which the composition is intended to be used.

The composition of the invention can have a melting point of from about 32°C to about 100°C depending on the function for which the composition is intended to be employed. If the composition is intended to be applied to an absorbent article, it may be desirable for the composition to have a melting point such that the composition is immobile at room temperature. Depending on the processing and handling to which the composition will be exposed, it may be beneficial for the composition to have a process viscosity less than about 100 centipoise under shear or pressure. Examples of specific compounds for the fat/oil, sterol/sterol derivative, emollient, solidifying agent and viscosity enhancer components of the composition can be as described previously and as will be described herein.

In an additional embodiment, the present invention is directed to a method for improving skin barrier function of a skin surface of a user. The method can include a step of contacting the skin surface of a user with a bodyfacing surface of a liner material. The liner material may be any type of woven or non-woven material. More specifically, the liner material is of a material that is typically used for the bodyside liner of an absorbent article. The bodyfacing surface of the liner material has a composition on it. The composition can include a natural fat or oil, a sterol or sterol derivative, an emollient, a solidifying agent and a viscosity enhancer. More specifically, the composition can include from about 0.1 to about 95 percent by weight of natural fats or oils, from about 0.1 to about 10 percent by weight of sterols or sterol derivatives, from about 1 to about 95 percent by weight of emollients, from about 5 to about 95 percent by weight of solidifying agents and from about 1 to about 25 percent by weight of viscosity enhancers.

The method can also include a step of maintaining the bodyfacing surface of the liner material in contact with the skin surface of a user for a sufficient amount of time to transfer the composition to the skin surface. For purposes of the method, a sufficient amount of time would be the amount of time necessary for enough of the composition to have been transferred so as to enhance the skin barrier. The method of the invention further includes a step of repeating contact of the skin surface with the bodyfacing surface of the liner material for a sufficient amount of time in order to have an improvement in the skin barrier function of the wearer's skin. The repeated contact can occur by either applying additional composition to the bodyfacing surface of the liner material or by applying a new liner material having a full amount of the composition on the bodyfacing surface.



The absorbent articles, methods and compositions of the invention advantageously enhance the skin barrier in such a way not observed with conventional absorbent articles and compositions. Consequently, use of the absorbent articles and compositions of the invention enhance the skin barrier to protect against damage caused by physical and biological irritations. It is to be understood that both the foregoing general description and the following detailed description are exemplary and are intended to provide further explanation of the invention claimed. The accompanying drawings, that are incorporated in and constitute part of this specification, are included to illustrate and provide a further understanding of the articles, methods and compositions of the invention. Together with the description, the drawings serve to explain the various aspects of the invention.

### **Brief Description of the Drawings**

The present invention will be more fully understood and further advantages will become apparent when reference is made to the following detailed description of the invention and the accompanying drawings. The drawings are merely representative and are not intended to limit the scope of the claims. Like parts of the absorbent articles depicted in the drawings are referred to by the same reference numerals.

Fig. 1 representatively shows a partially cut away, top plan view of an absorbent article according to one embodiment of the invention in a stretched and laid flat condition with the surface of the article that contacts the skin of the wearer facing the viewer;

Fig. 2 representatively shows a sectional view of the absorbent article of Fig. 1 taken along line 2—2; and

Fig. 3 representatively shows a top plan view of the bodyside liner of the absorbent article of Fig. 1 with the surface that contacts the wearer facing the viewer.

Fig. 4 graphically represents the relationship between viscosity and temperature for compositions of the invention and comparative compositions.

### **Detailed Description of the Invention**

The present invention is directed to solving problems related to enhancing the barrier function of the skin when the skin is exposed to causes of physical and biological damage. Similarly, the present invention is directed to solving problems related to the prevention and treatment of diaper rash.

The present invention encompasses compositions, compositions as they are applied to the bodyfacing materials of absorbent articles, absorbent articles including compositions and methods of applying compositions to absorbent articles. The following detailed description will be made in the context of one type of absorbent article, a disposable diaper that is adapted to be worn by infants about their lower torso. It is readily apparent, however, that the absorbent article of the present invention would also be suitable for use as another type of absorbent article, such as a feminine care pad, an incontinence garment, a training pant, a prefastened or refastenable diaper pant, a wound dressing or a nursing pad. Further, the compositions of the invention are not limited to application on the bodyfacing materials of absorbent articles. For example, the compositions of the inventions could be used on skin-contacting substrates such as tissues, wet (pre-moistened) wipe materials and cosmetic pads (such as for cleansing or buffing).

Fig. 1 is a representative plan view of a disposable diaper 10 of the present invention in a flat-out, uncontracted state (i.e., with all elastic induced gathering and contraction removed). The bodyfacing surface 11 of the diaper 10, that is, the surface 11 of the diaper 10 that contacts the wearer is facing the viewer. The compositions of the invention can be applied to one or more bodyfacing materials that are components of the diaper 10. As used herein, the term 'bodyfacing material' includes, but is not limited to, materials such as the bodyside liner or topsheet, elastic material, tissue, intake and distribution material, absorbent material, and backsheet material. Each of these materials and components of a diaper 10 are described more fully herein. The compositions of the invention are applied to one or more of the bodyfacing materials in order to have a beneficial effect on the skin barrier. The bodyfacing material of the present invention can be a single layer or multi-layered.

With reference to Fig. 1, the diaper 10 generally defines a front waist section 12, a rear waist section 14, and an intermediate section 16 that interconnects the front and rear waist sections 12 and 14. The front and rear waist sections 12 and 14 include the general portions of the diaper 10 that are constructed to extend substantially over the wearer's front and rear abdominal regions, respectively, during use. The intermediate section 16 of the diaper 10 includes the general portion of the diaper 10 that is constructed to extend through the wearer's crotch region between the legs.

The diaper 10 includes a vapor permeable backsheet or outer cover 20, a liquid permeable topsheet or bodyside liner 22 positioned in facing relation with the outer cover 20, and an absorbent body 24, such as an absorbent pad, which is located between the outer cover 20 and the bodyside liner 22. The outer cover 20 defines a length and a width

that, in the illustrated embodiment, coincide with the length and width of the diaper 10. The absorbent body 24 generally defines a length and width that are less than the length and width of the outer cover 20, respectively. Thus, marginal portions of the diaper 10, such as marginal sections of the outer cover 20, may extend past the terminal edges of the absorbent body 24. In the illustrated embodiments, for example, the outer cover 20 extends outwardly beyond the terminal marginal edges of the absorbent body 24 to form side margins and end margins of the diaper 10. The bodyside liner 22 is generally coextensive with the outer cover 20 but may optionally cover an area that is larger or smaller than the area of the outer cover 20, as desired. In other words, the bodyside liner 22 is connected in superposed relation to the outer cover 20. The outer cover 20 and bodyside liner 22 are intended to face the garment and body of the wearer, respectively, while in use.

To provide improved fit and to help reduce leakage of body exudates from the diaper 10, the diaper side margins and end margins may be elasticized with suitable elastic members, such as single or multiple strands of elastic. The elastic strands may be composed of natural or synthetic rubber and may optionally be heat shrinkable or heat elasticizable. For example, as representatively illustrated in Fig. 1, the diaper 10 may include leg elastics 26 which are constructed to operably gather and shirr the side margins of the diaper 10 to provide elasticized leg bands which can closely fit around the legs of the wearer to reduce leakage and provide improved comfort and appearance. Similarly, waist elastics 28 can be employed to elasticize the end margins of the diaper 10 to provide elasticized waists. The waist elastics 28 are configured to operably gather and shirr the waist sections to provide a resilient, comfortably close fit around the waist of the wearer. In the illustrated embodiments, the elastic members are illustrated in their uncontracted, stretched condition for the purpose of clarity.

Fastening means, such as hook and loop fasteners 30, are employed to secure the diaper 10 on a wearer. Alternatively, other fastening means, such as buttons, pins, snaps, adhesive tape fasteners, cohesives, mushroom-and-loop fasteners, or the like, may be employed. Additionally, more than two fasteners can be provided, particularly if the diaper 10 is to be provided in a prefastened configuration. The fasteners can vary in size and form.

The diaper 10 may further include other layers between the absorbent body 24 and the bodyside liner 22 or outer cover 20. For example, as representatively illustrated in Figs. 1 and 2, the diaper 10 may include a ventilation layer 32 located between the absorbent body 24 and the outer cover 20 to insulate the outer cover 20 from the absorbent body 24, to improve air circulation and to effectively reduce the dampness of

the garment facing surface of the outer cover 20. The ventilation layer 32 may also assist in distributing fluid exudates to portions of the absorbent body 24 that do not directly receive the insult. The diaper 10 may also include a surge management layer 34 located between the bodyside liner 22 and the absorbent body 24 to prevent pooling of the fluid exudates and further improve air exchange and distribution of the fluid exudates within the diaper 10.

The diaper 10 may be of various suitable shapes. For example, the diaper may have an overall rectangular shape, T-shape or an approximately hourglass shape. In the shown embodiment, the diaper 10 has a generally I-shape. The diaper 10 further defines a longitudinal direction 36 and a lateral direction 38. Other suitable diaper components that may be incorporated on absorbent articles of the present invention include containment flaps, waist flaps, elastomeric side panels, and the like which are generally known to those skilled in the art. Likewise, if the diaper 10 is to be sold in a prefastened condition, the diaper 10 may have passive bonds (not shown) that join the rear waist section 14 with the front waist section 12.

Examples of diaper configurations suitable for use in connection with the instant application that may include other diaper components suitable for use on diapers are described in U.S. Patent 4,798,603 issued January 17, 1989, to Meyer et al.; U.S. Patent 5,176,668 issued January 5, 1993, to Bernardin; U.S. Patent 5,176,672 issued January 5, 1993, to Bruemmer et al.; U.S. Patent 5,192,606 issued March 9, 1993, to Proxmire et al., and U.S. Patent 5,509,915 issued April 23, 1996 to Hanson et al., the disclosures of which are herein incorporated by reference.

The various components of the diaper 10 are integrally assembled together employing various types of suitable attachment means, such as adhesive, sonic bonds, thermal bonds or combinations thereof. In the shown embodiment, for example, the bodyside liner 22 and outer cover 20 are assembled to each other and to the absorbent body 24 with lines of adhesive, such as a hot melt, pressure-sensitive adhesive. Similarly, other diaper components, such as the elastic members 26 and 28, fastening members 30, and ventilation and surge layers 32 and 34 may be assembled into the diaper 10 by employing the above-identified attachment mechanisms.

The outer cover 20 of the diaper 10, as representatively illustrated in Fig. 1, is composed of a substantially vapor permeable material. The permeability of the outer cover 20 is configured to enhance the breathability of the diaper 10 and to reduce the hydration of the wearer's skin during use without allowing excessive condensation of vapor, such as urine, on the garment facing surface of the outer cover 20 that can undesirably dampen the wearer's clothes. The outer cover 20 is generally constructed to

be permeable to at least water vapor and has a water vapor transmission rate of at least about 1000 g/m<sup>2</sup>/24 hr., desirably at least about 1500 g/m<sup>2</sup>/24 hr, more desirably at least about 2000 g/m<sup>2</sup>/24 hr., and even more desirably at least about 3000 g/m<sup>2</sup>/24 hr. For example, the outer cover 20 may define a water vapor transmission rate of from about  
5 1000 to about 6000 g/m<sup>2</sup>/24 hr. Materials that have a water vapor transmission rate less than those above do not allow a sufficient amount of air exchange and undesirably result in increased levels of skin hydration.

The outer cover 20 is also desirably substantially liquid impermeable. For example, the outer cover 20 may be constructed to provide a hydrohead value of at least  
10 about 60 cm, desirably at least about 80 cm, and more desirably at least about 100 cm when subjected to the Hydrostatic Pressure Test. Materials that have hydrohead values less than those above undesirably result in the strike through of liquids, such as urine, during use. Such fluid strike through can undesirably result in a damp, clammy feeling on the outer cover 20 during use.

15 The outer cover 20 may be composed of any suitable materials that either directly provide the above desired levels of liquid impermeability and air permeability or, in the alternative, materials that can be modified or treated in some manner to provide such levels. In one embodiment, the outer cover 20 may be a nonwoven fibrous web constructed to provide the required level of liquid impermeability. For example, a  
20 nonwoven web composed of spunbond or meltblown polymer fibers may be selectively treated with a water repellent coating or laminated with a liquid impermeable, vapor permeable polymer film to provide the outer cover 20. In a particular embodiment of the invention, the outer cover 20 may include a nonwoven web composed of a plurality of randomly deposited hydrophobic thermoplastic meltblown fibers that are sufficiently  
25 bonded or otherwise connected to one another to provide a substantially vapor permeable and substantially liquid impermeable web. The outer cover 20 may also include a vapor permeable nonwoven layer that has been partially coated or otherwise configured to provide liquid impermeability in selected areas.

Examples of suitable materials for the outer cover 20 are also described in U.S.  
30 Patent No. 5,482,765 issued January 9, 1996 in the name of Bradley et al. and entitled "NONWOVEN FABRIC LAMINATE WITH ENHANCED BARRIER PROPERTIES"; U.S. Patent No. 5,879,341 issued March 9, 1999 in the name of Odorzynski et al. and entitled "ABSORBENT ARTICLE HAVING A BREATHABILITY GRADIENT"; U.S. Patent No. 5,843,056 issued December 1, 1998, in the name of Good et al. and entitled  
35 "ABSORBENT ARTICLE HAVING A COMPOSITE BREATHABLE BACKSHEET"; and U.S. Patent Application Serial No. 08/882,712 filed June 25, 1997, in the name of

McCormack et al. and entitled "LOW GAUGE FILMS AND FILM/NONWOVEN LAMINATES", the disclosures of which are herein incorporated by reference.

In a particular embodiment, the outer cover 20 is provided by a microporous film/nonwoven laminate material that includes a spunbond nonwoven material laminated to a microporous film. The spunbond nonwoven comprises filaments of about 1.8 denier extruded from a copolymer of ethylene with about 3.5 weight percent propylene and defines a basis weight of from about 17 to about 25 grams per square meter. The film comprises a cast coextruded film having calcium carbonate particles therein and defines a basis weight of about 58 grams per square meter prior to stretching. The film is preheated, stretched and annealed to form the micropores and then laminated to the spunbond nonwoven. The resulting microporous film/nonwoven laminate based material has a basis weight of from about 30 to about 60 grams per square meter and a water vapor transmission rate of from about 3000 to about 6000 g/m<sup>2</sup>/24 hr. Examples of such film/nonwoven laminate materials are described in more detail in U.S. Patent Application No. 08/882,712 filed June 25, 1997, in the name of McCormack et al. and entitled "LOW GAUGE FILMS AND FILM/NONWOVEN LAMINATES", the disclosure of which has been incorporated by reference.

In another embodiment, the outer cover 20 is provided by an extensible material. Further, the outer cover 20 can also be provided by a material having stretch in both the longitudinal 36 and lateral 38 directions. Extensible and stretchable outer cover materials can be used in absorbent articles to provide various benefits including better fitting articles.

The bodyside liner 22, as representatively illustrated in Figs. 1 and 2, defines a bodyfacing surface 11 that is compliant, soft feeling, and nonirritating to the wearer's skin. Further, the bodyside liner 22 may be less hydrophilic than the absorbent body 24, to present a relatively dry surface to the wearer, and may be sufficiently porous to be liquid permeable, permitting liquid to readily penetrate through its thickness. A suitable bodyside liner 22 may be manufactured from a wide selection of web materials, such as porous foams, reticulated foams, apertured plastic films, natural fibers (for example, wood or cotton fibers), synthetic fibers (for example, polyester or polypropylene fibers), or a combination of natural and synthetic fibers. The bodyside liner 22 is suitably employed to help isolate the wearer's skin from liquids held in the absorbent body 24.

Various woven and nonwoven fabrics can be used for the bodyside liner 22. For example, the bodyside liner 22 may be composed of a meltblown or spunbond web of polyolefin fibers. The bodyside liner 22 may also be a bonded-carded web composed of natural and/or synthetic fibers. The bodyside liner 22 may be composed of a substantially

hydrophobic material, and the hydrophobic material may, optionally, be treated with a surfactant or otherwise processed to impart a desired level of wettability and hydrophilicity. In a particular embodiment of the present invention, the bodyside liner 22 comprises a nonwoven, spunbond, polypropylene fabric composed of about 2.8-3.2 denier fibers  
5 formed into a web having a basis weight of about 22 grams per square meter and a density of about 0.06 gram per cubic centimeter.

In a particular embodiment of the present invention, the bodyside liner 22 may be surface treated with about 0.3 weight percent of a surfactant mixture that contains a mixture of AHCOVEL Base N-62 and GLUCOPON 220UP surfactants in about a 3:1 ratio  
10 based on a total weight of the surfactant mixture. The AHCOVEL Base N-62 surfactant is purchased from Hodgson Textile Chemicals Inc., a business having offices in Mount Holly, North Carolina, and includes a blend of hydrogenated ethoxylated castor oil and sorbitan monooleate in a 55:45 weight ratio. The GLUCOPON 220UP surfactant is purchased  
15 from Henkel Corporation and includes alkyl polyglycoside. The surfactant may also include additional ingredients such as aloe. The surfactant may be applied by any conventional means, such as spraying, printing, brush coating, foam or the like. The surfactant may be applied to the entire bodyside liner 22 or may be selectively applied to particular sections of the bodyside liner 22, such as the medial section along the longitudinal centerline of the diaper, to provide greater wettability of such sections.

20 The absorbent body 24 of the diaper 10, as representatively illustrated in Fig. 1, may suitably comprise a matrix of hydrophilic fibers, such as a web of cellulosic fluff, mixed with particles of a high-absorbency material commonly known as superabsorbent material. In a particular embodiment, the absorbent body 24 includes a matrix of cellulosic fluff, such as wood pulp fluff, and superabsorbent hydrogel-forming particles. The wood  
25 pulp fluff may be exchanged with synthetic, polymeric, meltblown fibers or with a combination of meltblown fibers and natural fibers. The superabsorbent particles may be substantially homogeneously mixed with the hydrophilic fibers or may be nonuniformly mixed. Alternatively, the absorbent body 24 may include a laminate of fibrous webs and superabsorbent material or other suitable matrix for maintaining a superabsorbent material  
30 in a localized area.

The absorbent body 24 may have any of a number of shapes. For example, the absorbent body 24 may be rectangular, I-shaped, or T-shaped. It is generally preferred that the absorbent body 24 is narrower in the intermediate section than in the front or rear waist sections of the diaper 10. The absorbent body 24 may be provided by a single layer  
35 or, in the alternative, may be provided by multiple layers, all of which need not extend the entire length and width of the absorbent body 24. In a particular aspect of the invention,

the absorbent body 24 can be generally T-shaped with the laterally extending cross-bar of the "T" generally corresponding to the front waist section 12 of the absorbent article for improved performance, especially for male infants. In the illustrated embodiments, for example, the absorbent body 24 across the front waist section 12 of the article has a cross-directional width of about 18 centimeters, the narrowest portion of the intermediate section 16 has a width of about 7.5 centimeters and in the rear waist section 14 has a width of about 11.4 centimeters.

The size and the absorbent capacity of absorbent body 24 should be compatible with the size of the intended wearer and the liquid loading imparted by the intended use of the absorbent article. Further, the size and the absorbent capacity of the absorbent body 24 can be varied to accommodate wearers ranging from infants through adults. In addition, it has been found that with the present invention, the densities and/or basis weights of the absorbent body 24 can be varied. In a particular aspect of the invention, the absorbent body 24 has an absorbent capacity of at least about 300 grams of synthetic urine.

In embodiments wherein the absorbent body 24 includes the combination of hydrophilic fibers and high-absorbency particles, the hydrophilic fibers and high-absorbency particles can form an average basis weight for the absorbent body 24 that is within the range of about 400-900 grams per square meter. In certain aspects of the invention, the average composite basis weight of such an absorbent body 24 is within the range of about 500-800 grams per square meter, and preferably is within the range of about 550-750 grams per square meter to provide the desired performance.

To provide the desired thinness dimension to the various configurations of the absorbent article of the invention, the absorbent body 24 can be configured with a bulk thickness that is not more than about 0.6 centimeters. Preferably, the bulk thickness is not more than about 0.53 centimeters, and more preferably is not more than about 0.5 centimeters to provide improved benefits. The bulk thickness is determined under a



Examples of synthetic, polymeric, high-absorbency materials include the alkali metal and ammonium salts of poly(acrylic acid) and poly(methacrylic acid), poly(acrylamides), poly(vinyl ethers), maleic anhydride copolymers with vinyl ethers and alpha-olefins, poly(vinyl pyrrolidone), poly(vinyl morpholinone), poly(vinyl alcohol), and mixtures and copolymers thereof. Further polymers suitable for use in the absorbent body 24 include natural and modified natural polymers, such as hydrolyzed acrylonitrile-grafted starch, acrylic acid grafted starch, methyl cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, and the natural gums, such as alginates, xanthan gum, locust bean gum, and the like. Mixtures of natural and wholly or partially synthetic absorbent polymers can also be useful in the present invention.

The high absorbency material may be in any of a wide variety of geometric forms. As a general rule, it is preferred that the high absorbency material be in the form of discrete particles. However, the high absorbency material may also be in the form of fibers, flakes, rods, spheres, needles, or the like. In general, the high absorbency material is present in the absorbent body 24 in an amount of from about 5 to about 90 percent by weight, desirably in an amount of at least about 30 percent by weight, and even more desirably in an amount of at least about 50 percent by weight based on a total weight of the absorbent body 24. For example, in a particular embodiment, the absorbent body 24 may include a laminate which includes at least about 50 percent by weight and desirably at least about 70 percent by weight of high-absorbency material overwrapped by a fibrous web or other suitable material for maintaining the high-absorbency material in a localized area.

An example of high-absorbency material suitable for use in the present invention is SANWET IM 3900 polymer available from Hoechst Celanese, a business having offices in Portsmouth, Virginia. Other suitable superabsorbents may include FAVOR SXM 880 polymer obtained from Stockhausen, a business having offices in Greensboro, North Carolina.

Optionally, a substantially hydrophilic tissue wrapsheet (not illustrated) may be employed to help maintain the integrity of the structure of the absorbent body 24. The tissue wrapsheet is typically placed about the absorbent body 24 over at least the two major facing surfaces thereof. The tissue wrapsheet can be composed of an absorbent cellulosic material, such as creped wadding or a high wet-strength tissue. In one aspect of the invention, the tissue wrapsheet can be configured to provide a wicking layer that helps to rapidly distribute liquid over the mass of absorbent fibers constituting the absorbent body 24.

The absorbent body 24 of the different aspects of the present invention further includes a plurality of zones of high air permeability which allow air and vapors to readily pass through the absorbent body 24 and through the vapor permeable outer cover 20 out of the diaper 10 into ambient air. For example, the absorbent body 24 may include a plurality of air passageways that provide the absorbent body 24 with zones or regions of high air permeability. The portions of the absorbent body 24 adjacent the air passageways provide zones or regions of high absorption. The zones of high air permeability are designed to provide the maximum air exchange from the absorbent body 24 while the zones of high absorption are designed to receive and hold the majority of the body exudates. The absorbent body 24 may define any number of zones of high air permeability that provide the improved air exchange. Desirably, the absorbent body 24 defines at least 3 and more desirably at least 5 different zones of high air permeability for improved performance.

The zones of high air permeability, such as the air passageways, are configured to enhance the breathability of the article to reduce the hydration of the wearer's skin during use without allowing excessive condensation of vapor, such as urine, on the garment facing surface of the outer cover 20. Such condensation of vapor on the outer surface of the diaper 10 can undesirably dampen the wearer's clothes. The zones of high air permeability are generally located in the area of the diaper over which air and vapor can transfer from the bodyside liner 22, through the absorbent body 24 and any other intervening layer or layers of material, and out the vapor permeable outer cover 20. For example, the zones of high air permeability may be located throughout the entire absorbent body 24 or may be selectively located in those regions of the absorbent body 24 that provide the maximum air exchange, such as the intermediate section 16 of the diaper 20. In a particular embodiment, the zones of high air permeability are located in the front and intermediate sections 12 and 16, respectively, of the diaper 10 for improved air exchange.

The zones of high absorption, on the other hand, are not designed to transfer a high level of air and vapor from the interior of the diaper 10. Thus, the air exchange from the bodyside liner 22 of the diaper 10 to the outer cover 20 of the diaper and into the ambient atmosphere (exterior of the diaper 10) occurs generally through the absorbent body 24 in the zones of high air permeability. Some air exchange through the absorbent body 24 can also occur in the zones of high absorption to a limited degree. The zones of high air permeability may have any desired configuration including rectangular, circular, hourglass, oval, and the like, and may also include selected longitudinal or lateral strips or multiple regions which may be intermittently located.

The zones of high air permeability may have any desired dimensions that effectively provide improved air exchange while preventing excessive condensation of vapor from the absorbent body 24 through and onto the garment facing surface of the outer cover 20. Desirably, the zones of high air permeability may define a total area of  
5 from about 5 to about 75 percent, more desirably at least about 10 percent, even more desirably from about 10 to about 70 percent, and still more desirably from about 10 to about 60 percent of the total surface area of the absorbent body 24 of the diaper 10. For example, in a diaper 10 intended for use on a medium sized infant, the zones of high air permeability may define a total area of from about 6 to about 90 square centimeters.

10 When the total area of the zones of high air permeability is greater than the above amounts, the diaper 10 may exhibit an undesirable amount of condensation of vapor on the exposed, garment facing surface of the outer cover 20 undesirably resulting in a clammy feeling on the outer surface of the diaper 10. Whereas, when the total area of the zones of high air permeability is less than the above amounts, the diaper 10 may exhibit a  
15 low level of air exchange resulting in high levels of skin hydration that can undesirably lead to skin irritation and rash.

The zones of high air permeability of the absorbent body 24 of the diaper 10 are constructed to be substantially permeable to at least air and preferably permeable to water vapor. For example, the zones of high air permeability of the absorbent body 24 define a  
20 Frazier Porosity value which is at least about 10 percent, more desirably at least about 20 percent and even more desirably at least about 50 percent greater than the Frazier Porosity value of the zones of high absorption of the absorbent body 24. As used herein, the term "Frazier Porosity" refers to the value determined according to the Frazier Porosity Test set forth below. When the zones of high air permeability exhibit Frazier Porosity  
25 values less than those indicated above, the diaper 10 may exhibit a low level of air exchange resulting in high levels of skin hydration that can undesirably lead to skin irritation and rash.

The zones of high air permeability may be provided in a variety of ways. The zones of high air permeability may be integral portions of the absorbent body 24 of the  
30 absorbent article or may be provided by apertures, holes or open spaces in the absorbent body 24. For example, portions of the absorbent body 24 may be discontinuous or removed to provide the zones. Alternatively, the zones of high air permeability may be provided by portions of the absorbent body 24 that are constructed to absorb less fluid exudates thereby resulting in improved air flow through such portions in use. For  
35 example, portions of the absorbent body 24 may be void of or contain substantially less high-absorbency material than other portions of the absorbent body 24 to provide such

improved air flow. Portions of the absorbent body 24 may otherwise be treated or coated with a solution that renders them hydrophobic to provide the zones of high air permeability in selected areas. In other alternative configurations, the zones of high air permeability may be provided by creating voids or holes in the absorbent body 24 and placing other materials having a higher air permeability than the absorbent body 24, such as those materials described below as being suitable for the surge management layer 34, in the holes or voids.

Due to the thinness of absorbent body 24 and the high absorbency material within the absorbent body 24, the liquid uptake rates of the absorbent body 24, by itself, may be too low, or may not be adequately sustained over multiple insults of liquid into the absorbent body 24. To improve the overall liquid uptake and air exchange, the diaper of the different aspects of the present invention may further include a porous, liquid-permeable layer of surge management material 34, as representatively illustrated in Fig. 1. The surge management layer 34 is typically less hydrophilic than the absorbent body 24, and has an operable level of density and basis weight to quickly collect and temporarily hold liquid surges, to transport the liquid from its initial entrance point and to substantially completely release the liquid to other parts of the absorbent body 24. This configuration can help prevent the liquid from pooling and collecting on the portion of the diaper positioned against the wearer's skin, thereby reducing the feeling of wetness by the wearer. The structure of the surge management layer 34 also generally enhances the air exchange within the diaper 10.

Various woven and nonwoven fabrics can be used to construct the surge management layer 34. For example, the surge management layer 34 may be a layer composed of a meltblown or spunbond web of synthetic fibers, such as polyolefin fibers. The surge management layer 34 may also be a bonded-carded-web or an airlaid web composed of natural and synthetic fibers. The bonded-carded-web may, for example, be a thermally bonded web that is bonded using low melt binder fibers, powder or adhesive. The webs can optionally include a mixture of different fibers. The surge management layer 34 may be composed of a substantially hydrophobic material, and the hydrophobic material may optionally be treated with a surfactant or otherwise processed to impart a desired level of wettability and hydrophilicity. In a particular embodiment, the surge management layer 34 includes a hydrophobic, nonwoven material having a basis weight of from about 30 to about 120 grams per square meter.

For example, in a particular embodiment, the surge management layer 34 may include a bonded-carded-web, nonwoven fabric that includes bicomponent fibers and that defines an overall basis weight of about 83 grams per square meter. The surge

management layer 34 in such a configuration can be a homogeneous blend composed of about 60 weight percent polyethylene/polyester (PE/PET), sheath-core bicomponent fibers that have a fiber denier of about 3 d and about 40 weight percent single component polyester fibers that have a fiber denier of about 6 d and that have fiber lengths of from  
5 about 3.8 to about 5.08 centimeters.

In the illustrated embodiments, the surge management layer 34 is arranged in a direct, contacting liquid communication with the absorbent body 24. The surge management layer 34 may be operably connected to the bodyside liner 22 with a conventional pattern of adhesive, such as a swirl adhesive pattern. In addition, the surge  
10 management layer 34 may be operably connected to the absorbent body 24 with a conventional pattern of adhesive. The amount of adhesive add-on should be sufficient to provide the desired levels of bonding, but should be low enough to avoid excessively restricting the movement of liquid from the bodyside liner 22, through the surge management layer 34 and into the absorbent body 24.

15 The absorbent body 24 is positioned in liquid communication with surge management layer 34 to receive liquids released from the surge management layer 34, and to hold and store the liquid. In the shown embodiment, the surge management layer 34 includes a separate layer that is positioned over another, separate layer including the absorbent body 24, thereby forming a dual-layer arrangement. The surge management  
20 layer 34 serves to quickly collect and temporarily hold discharged liquids, to transport such liquids from the point of initial contact and spread the liquid to other parts of the surge management layer 34, and then to substantially completely release such liquids into the layer or layers constituting the absorbent body 24.

The surge management layer 34 can be of any desired shape. Suitable shapes  
25 include for example, circular, rectangular, triangular, trapezoidal, oblong, dog-boned, hourglass-shaped, or oval. In certain embodiments, for example, the surge management layer 34 can be generally rectangular-shaped. In the illustrated embodiments, the surge management layer 34 is coextensive with the absorbent body 24. Alternatively, the surge management layer 34 may extend over only a part of the absorbent body 24. Where the  
30 surge management layer 34 extends only partially along the length of the absorbent body 24, the surge management layer 34 may be selectively positioned anywhere along the absorbent body 24. For example, the surge management layer 34 may function more efficiently when it is offset toward the front waist section 12 of the diaper 10. The surge management layer 34 may also be approximately centered about the longitudinal center  
35 line of the absorbent body 24.

Additional materials suitable for the surge management layer 34 are set forth in U.S. Patent No. 5,486,166 issued January 23, 1996 in the name of C. Ellis et al. and entitled "FIBROUS NONWOVEN WEB SURGE LAYER FOR PERSONAL CARE ABSORBENT ARTICLES AND THE LIKE"; U.S. Patent No. 5,490,846 issued February 13, 1996 in the name of Ellis et al. and entitled "IMPROVED SURGE MANAGEMENT FIBROUS NONWOVEN WEB FOR PERSONAL CARE ABSORBENT ARTICLES AND THE LIKE"; and U.S. Patent No. 5,364,382 issued November 15, 1994 in the name of Latimer et al. and entitled "ABSORBENT STRUCTURE HAVING IMPROVED FLUID SURGE MANAGEMENT AND PRODUCT INCORPORATING SAME", the disclosures of which are hereby incorporated by reference.

As representatively illustrated in Fig. 1, the diaper 10 may also include a ventilation layer 32 located between the outer cover 20 and the absorbent body 24. The ventilation layer 32 serves to facilitate the movement of air within and through the diaper 10 and prevent the outer cover 20 from being in surface to surface contact with at least a portion of the absorbent body 24. Specifically, the ventilation layer 32 serves as a conduit through which air and water vapor can move from the absorbent body 24 through the vapor permeable outer cover 20.

The ventilation layer 32 may be formed from materials described above as being suitable for the surge management layer 34 such as nonwoven, (e.g., spunbond, meltblown or carded), woven, or knitted fibrous webs composed of natural fibers and/or synthetic polymeric fibers. Suitable fibers include, for example, acrylic fibers, polyolefin fibers, polyester fibers, or blends thereof. The ventilation layer 32 may also be formed from a porous foam material such as an open-celled polyolefin foam, a reticulated polyurethane foam, and the like. The ventilation layer 32 may include a single layer of material or a composite of two or more layers of material. In a particular embodiment, the ventilation layer 32 includes a hydrophobic, nonwoven material having a thickness of at least about 0.10 centimeters determined under a restraining pressure of 0.05 psi (0.34 kPa) and a basis weight of from about 20 to about 120 grams per square meter. For example, the ventilation layer 32 may comprise a bonded-carded-web, nonwoven fabric that includes bicomponent fibers and that defines an overall basis weight of about 83 grams per square meter. The ventilation layer 32 in such a configuration can be a homogeneous blend composed of about 60 weight percent polyethylene/polyester (PE/PET), sheath-core bicomponent fibers that have a fiber denier of about 3 d and about 40 weight percent single component polyester fibers that have a fiber denier of about 6 d and that have fiber lengths of from about 3.8 to about 5.08 centimeters.

The ventilation layer 32 can be of any desired shape. Suitable shapes include for example, circular, rectangular, triangular, trapezoidal, oblong, dog-boned, hourglass-shaped, or oval. The ventilation layer 32 may extend beyond, completely over or partially over the absorbent body 24. For example, the ventilation layer 32 may suitably be located  
5 over the intermediate section 16 of the diaper 10 and be substantially centered side-to-side with respect to the longitudinal centerline 36 of the diaper 10. It is generally desired that the entire absorbent body 24 be overlaid with the ventilation layer 32 to prevent substantially all surface to surface contact between the outer cover 20 and the absorbent body 24. In the illustrated embodiments, the ventilation layer 32 is coextensive with the  
10 absorbent body 24. This allows for the maximum degree of air exchange with minimal dampness on the garment facing surface of the outer cover 20.

In the illustrated embodiments, the ventilation layer 32 is arranged in a direct, contacting liquid communication with the absorbent body 24. The ventilation layer 32 may be operably connected to the outer cover 20 with a conventional pattern of adhesive, such  
15 as a swirl adhesive pattern. In addition, the ventilation layer 32 may be operably connected to the absorbent body 24 with a conventional pattern of adhesive. The amount of adhesive add-on should be sufficient to provide the desired levels of bonding, but should be low enough to avoid excessively restricting the movement of air and vapor from the absorbent body 24 and through the outer cover 20.

20 The ventilation layer 32 may further serve to quickly collect and temporarily hold discharged liquids, which pass through the absorbent body 24 and, in particular, through the zones of high air permeability within the absorbent body 24. The ventilation layer 32 may then transport such liquids from the point of initial contact and spread the liquid to other parts of the ventilation layer 32, and then substantially completely release such  
25 liquids into the layer or layers of the absorbent body 24.

In order to maintain and enhance the barrier of the skin covered by the diaper 10, a composition is applied to the bodyfacing surface 11 of the bodyside liner 22 of the diaper 10. The composition generally can include natural fats or oils, sterols or sterol derivatives, emollient(s), solidifying agent(s) and viscosity enhancer(s). Additionally, the composition  
30 can include a rheology modifier. For example, the compositions of the invention may include from about 0.1 to about 95 percent by weight of one or more natural fats or oils; from about 0.1 to about 10 percent by weight of one or more sterols or sterol derivatives; from about 1 to about 95 percent by weight of one or more emollients; from about 5 to about 95 percent by weight of one or more solidifying agents; and, from about 0.1 to about  
35 25 percent by weight of one or more viscosity enhancers. The composition may include other ingredients as well. Ranges are used to describe the relative amounts of

components in the compositions of the invention as well as to describe the relative physical properties of the compositions. These ranges are illustrative and one of skill in the art will recognize that the nature of the composition will dictate the various levels of components that must be used to achieve the intended benefit for the skin barrier. The levels can be determined by routine experimentation in view of the disclosure provided herein.

The compositions of the invention can be in a variety of physical forms including emulsions, lotions, creams, ointments, salves, suspensions, gels or hybrids of these forms.

The compositions of the invention can include fats and oils that provide a source of essential and non-essential fatty acids similar to those found in the skin's natural barrier. Fats and oils include compounds that are fats, oils, essential oils, fatty acids, fatty alcohols, phospholipids and mixtures of such compounds. Fats and oils include oils derived from plant and animal sources. Similarly, the essential oils include essential oils derived from plant sources. Those of skill in the art would understand that all compounds commonly understood to have the structure of or to function as fats, oils, essential oils, fatty acids, fatty alcohols and phospholipids can be used as the natural fat or oil component of the composition of the invention. While an exhaustive list of each and every fat and oil that could be used in the compositions of the invention is not provided, those of skill in the art will understand and appreciate the individual compounds that can serve as a fat or oil component of the compositions of the invention.

Representative examples of fats and oils include, but are not limited to: Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lanolin, Lanolin Alcohol, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Behenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, and Soybean Oil. Another suitable fat/oil for the compositions of the invention is PROLIPID 141 blend available from International Specialty Products of Wayne, New Jersey. The PROLIPID 141 blend is a mixture of glyceryl stearate, fatty acids, fatty alcohols and phospholipids.

In order to assist in replenishing skin barrier enhancing agents, the compositions of the invention may include fats and oils in an amount of from about 0.1 to about 95 percent



by weight, desirably from about 5 to about 75 percent by weight, and more desirably from about 10 to about 50 percent by weight of the composition.

The compositions of the invention also include sterols and sterol derivatives that act in combination with the natural fats/oils to provide natural skin barrier enhancement and skin barrier recovery. Sterols and sterol derivatives that can be used in the compositions of the invention include, but are not limited to:  $\beta$ -sterols having a tail on the 17 position and having no polar groups for example, cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C<sub>10</sub>-C<sub>30</sub> cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, "AVOCADIN" (trade name of Croda Ltd of Parsippany, New Jersey), sterol esters and similar compounds, as well as mixtures thereof. The compositions of the invention can include sterols, sterol derivatives or mixtures of both sterols and sterol derivatives in an amount of from about 0.1 to about 10 percent by weight, desirably from about 0.5 to about 5 percent by weight and more desirably from about 0.8 to about 1 percent by weight of the composition.

The emollients of the compositions act as lubricants to reduce the abrasiveness of the bodyside liner 22 to the skin and, upon transfer to the skin, help to maintain the soft, smooth and pliable appearance of the skin. Suitable emollients that can be incorporated into the compositions include oils such as petroleum based oils, petrolatum, vegetable based oils, mineral oils, natural or synthetic oils, alkyl dimethicones, alkyl methicones, alkyldimethicone copolyols, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin and its derivatives, fatty esters, glycerol esters and derivatives, propylene glycol esters and derivatives, alkoxyated carboxylic acids, alkoxyated alcohols, fatty alcohols and mixtures of such compounds. The esters can be selected from cetyl palmitate, stearyl palmitate, cetyl stearate, isopropyl laurate, isopropyl myristate, isopropyl palmitate and mixtures thereof. Ethers such as eucalyptol, cetearyl glucoside, dimethyl isosorbicide polyglyceryl-3 cetyl ether, polyglyceryl-3 decyltetradecanol, propylene glycol myristyl ether and mixtures thereof can also be used as emollients. The fatty alcohols include octyldodecanol, lauryl, myristyl, cetyl, stearyl and behenyl alcohol and mixtures thereof. For example, a particularly well suited emollient is petrolatum. Other conventional emollients may also be added in a manner that maintains the desired properties of the compositions set forth herein.

To provide improved stability and transfer to the skin of the wearer, the compositions may include from about 1 to about 95 percent by weight, desirably from

about 20 to about 75 percent by weight, and more desirably from about 40 to about 60 percent by weight of the emollient. Compositions that include an amount of emollient greater than the recited amounts tend to have lower viscosities that undesirably lead to migration of the composition. Whereas, compositions that include an amount of emollient less than the recited amounts tend to provide less transfer to the wearer's skin.

The solidifying agent(s) in the compositions of the present invention primarily functions to solidify the composition so that the composition is a solid at room temperature and has a penetration hardness of at least 5 mm and a melting point of at least 32°C. The solidifying agent also provides a tackiness to the composition that improves the transfer to the skin of the wearer. Depending on the solidifying agent selected, the solidifying agent can also modify the mode of transfer so that the composition tends to fracture or flake off instead of actually rubbing off onto the skin of the wearer which can lead to improved transfer to the skin. The solidifying agent may further function as an emollient, occlusive agent, moisturizer, barrier enhancer and combinations thereof. The solidifying agents may include waxes as well as compounds that perform functionally as waxes.

The solidifying agents can be selected from alkyl siloxanes, polymers, hydrogenated vegetable oils having a melting point of 35°C or greater and fatty acid esters with a melting point of 35°C or greater. Additionally, the solidifying agents can be selected from animal, vegetable and mineral waxes and alkyl silicones. Examples of solidifying agents include, but are not limited to, the following: alkyl trimethylsilanes, beeswax, C<sub>24</sub>-C<sub>28</sub> alkyl dimethicone, C<sub>30</sub> alkyl dimethicone, cetyl methicone, stearyl methicone, cetyl dimethicone, stearyl dimethicone, ceretyl dimethicone, candelilla wax, carnauba, cerasin, hydrogenated microcrystalline wax, jojoba wax, microcrystalline wax, lanolin wax, ozokerite, paraffin, spermaceti wax, cetyl esters, behenyl behenate, C<sub>20</sub>-C<sub>40</sub> alkyl behenate, C<sub>12</sub>-C<sub>15</sub> lactate, cetyl palmitate, stearyl palmitate, isosteryl behenate, lauryl behenate, stearyl benzoate, behenyl isostearate, cetyl myristate, cetyl octanoate, cetyl oleate, cetyl ricinoleate, cetyl stearate, decyl oleate, di-C<sub>12</sub>-C<sub>15</sub> alkyl fumerate, dibehenyl fumerate, myristyl lactate, myristyl lignocerate, myristyl myristate, myristyl stearate, lauryl stearate, octyldodecyl stearate, octyldodecyl stearyl stearate, oleyl arachidate, oleyl stearate, tridecyl behenate, tridecyl stearate, tridecyl stearyl stearate, pentaerythrityl tetrabehenate, pentaerythrityl hydrogenated rosinatate, pentaerythrityl distearate, pentaerythrityl tetraabete, pentaerythrityl tetracocoate, pentaerythrityl tetraerlargonate, pentaerythrityl tetrastearate, ethylene vinyl acetate, polyethylene, hydrogenated vegetable oil, hydrogenated squalene, hydrogenated coconut oil, hydrogenated jojoba oil, hydrogenated palm oil, hydrogenated palm kernel oil, hydrogenated olive oil, polyamides, metal stearates and other metal soaps, C<sub>30</sub>-C<sub>60</sub> fatty alcohols, C<sub>20</sub>+ fatty amides,

polypropylene, polystyrene, polybutane, polybutylene terephthalate, polydipentane, polypropylene, zinc stearate and mixtures of such compounds. In one embodiment, the solidifying agent is a blend including about 70 weight percent cerasin wax, about 10 weight percent microcrystalline wax, about 10 weight percent paraffin wax and about 10 weight percent cetyl esters (synthetic spermaceti wax).

Appropriate solidifying agents also include alkylmethysiloxanes that can be described as non-volatile, occlusive silicone-aliphatic hydrocarbon hybrid waxes. An example of an alkylmethysiloxane wax is a poly(n-alkylmethysiloxane)dimethylsiloxane. The poly(n-alkylmethysiloxane)dimethylsiloxane can have an n-alkyl substitution of an average of 16 carbon atoms or above with an average of more than 2 alkyl groups per molecule, with hydrocarbon contents of at least 40% and with an average molecular weight of at least 1800 or higher. Examples of desirable alkylmethysiloxanes for use in the compositions of the invention include random copolymers having the following formula:



The "R" component of the formula can be an aliphatic hydrocarbon substituent where the chain length is from C<sub>4</sub> to C<sub>45</sub>. In particular, "R" can be C<sub>16</sub>, C<sub>16-18</sub>, C<sub>20-24</sub> or C<sub>30-45</sub>. For example, C<sub>30-45</sub> alkylmethysiloxane is commercially available as trade designation "SF1642" from General Electric Silicones or "AMS-C<sub>30</sub>" from Dow Corning Silicones. The value of "x" is on average more than 2 and the value of "y" is at least 1. The nature of the alkylmethysiloxane must be balanced between its compatibility with dimethicone or polydimethyl siloxane and its compatibility with organic compounds like petrolatum and waxes. For example, as "x" increases, "y" decreases and "R" is small, the molecule increases its compatibility with dimethicone but decreases its compatibility with organic compounds. Alternatively, as "x" decreases, "y" increases and "R" is C<sub>18+</sub>, the molecule decreases its compatibility with dimethicone but increases its compatibility with organic compounds. These solidifying agents can be used to stabilize dimethicone-containing compositions of the invention.

To provide improved transfer to the skin of the wearer, the composition may include from about 5 to about 95 percent by weight, desirably from about 25 to about 75 percent by weight, and more desirably from about 30 to about 50 percent by weight of solidifying agent(s). Compositions that include an amount of solidifying agent less than the recited amounts tend to be too soft and may have lower viscosities that may undesirably lead to migration of the composition away from bodyfacing surfaces 11 of the absorbent article, thus diminishing transfer to the wearer's skin. Whereas, compositions

that include an amount of solidifying agent greater than the recited amounts tend to provide less transfer to the wearer's skin.

One or more viscosity enhancers may be added to the composition to increase the viscosity, to help stabilize the formulation on the bodyfacing surface 11 of the bodyside liner 22 and, thereby, to reduce migration and improve transfer to the skin. The viscosity enhancer increases the meltpoint viscosity of the compositions to have viscosity at the "hot box car" stability temperature of about 54.5°C. Having viscosity at elevated temperatures prevents the compositions from migrating into or away from the materials to which they are applied. However, the viscosity enhancer component also provides a low viscosity (<200 centipoise) for the compositions at process temperatures. Typically, process temperatures are approximately 5°C above the melting point of the composition. Examples of suitable viscosity enhancers include polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, polyethylene, silica, silica silylate, silica methyl silylate, colloidal silicone dioxide, cetyl hydroxy ethyl cellulose, other organically modified celluloses, PVP/decane copolymer, PVM/MA decadiene crosspolymer, PVP/eicosene copolymer, PVP/hexadecane copolymer and mixtures of these compounds. A particularly well suited viscosity enhancer is an ethylene/vinyl acetate copolymer commercially available from E. I. Dupont De Ne Mours under the trade designation "ELVAX".

To provide the improved transfer to the skin of the wearer, the composition may include from about 0.1 to about 25 percent by weight, desirably from about 3 to about 20 percent by weight, and more desirably from about 5 to about 10 percent by weight of the viscosity enhancer for reduced migration and improved transfer to the wearer's skin.

An example of the benefit provided by the viscosity enhancers of the invention is illustrated in Fig. 4. Fig. 4 is a graph of the relationship between viscosity and temperature for compositions of the invention and comparative compositions. The viscosity v. temperature relationship is plotted for six compositions: (1) "Ozokerite Wax" is a blend of microcrystalline wax, paraffin wax, cetyl esters and mineral oil; (2) "Ozokerite 7% Resin" is ozokerite wax plus 7% ELVAX resin; (3) "Ozokerite 15% Resin" is ozokerite wax plus 15% ELVAX resin; (4) "Example 1" is a mixture of 52.45% petrolatum, 2.5% octododecanol, 38.3% ozokerite wax and 6.75% ELVAX 410 resin; (5) "Example 2" is a mixture of 80% petrolatum and 20% stearyl alcohol; and (6) "Example 3" is a mixture of 50% petrolatum, 10% cetyl esters, 10% hydrogenated cottonseed oil and 30% cerasin wax. The plotted viscosity values at the three temperatures are as provided in Table 1. below.

Table 1.

Formulation	Viscosity at 55°C (in centipoise)	Viscosity at 60°C (in centipoise)	Viscosity at 65°C (in centipoise)
Ozokerite Wax	25	16	13
Ozokerite 7% Resin	80	30	25
Ozokerite 15% Resin	100	68	47
Example 1	100,000 *	151	64
Example 2	10	5	3
Example 3	115	11	7

\* this value is an artificial value used to indicate that the viscosity increased sharply and was too viscous to be measured.

- 5 As seen in Fig. 4, each of the compositions has a relatively low viscosity at 65°C. Except for Example 1, each of the compositions experiences only moderate increases in viscosity as temperature is lowered toward 55°C. Example 1, however, which represents a composition of the invention, including a viscosity enhancer, experiences a relatively dramatic increase in viscosity between 65°C and 60°C. At 55°C, Example 1 has a
- 10 viscosity too high to be measured by the internal techniques that were applied. The "Ozokerite 7% Resin" and "Ozokerite 15% Resin" also have ELVAX resin, a viscosity enhancer of the invention, however their viscosity does not increase significantly between 65°C and 55°C. This suggests that the viscosity enhancer (ELVAX resin) is more compatible with the Ozokerite wax by itself at temperatures above 55°C (compared to its
- 15 compatibility with "Example 1"). In other words, taking a wax that is very compatible with a viscosity enhancer such as ELVAX resin, there is a temperature-solubility curve. As the resin is heated in the presence of the wax or organic material, the resin becomes more soluble and does not affect the viscosity of the mixture. Upon cooling, however, the resin becomes less soluble and begins to form a "network" as it cools, thereby increasing the
- 20 viscosity of the mixture. With "Example 1", the viscosity enhancer is less soluble than it is in the Ozokerite wax and starts to come out of solution more rapidly than it does in the Ozokerite wax. Therefore, a better "network" develops and there is a significantly increase in viscosity. Approximately 55°C is the temperature for "hot box car" stability (the stability temperature for surviving potential transportation and storage temperatures).
- 25 Approximately 60°C and above represents processing temperatures. Therefore, the compositions of the invention can be processed at very low viscosities, but when the compositions are applied to a bodyfacing surface 11 of an absorbent article, they cool very rapidly and the viscosity increases very rapidly before the composition is completely

solidified. The rapid increase in viscosity helps to maintain the compositions on the bodyfacing surfaces 11.

In addition to one or more viscosity enhancers, the compositions of the invention may also include one or more rheology modifiers. Rheology modifiers are compounds that increase the viscosity of the compositions at lower temperatures as well as process temperatures. Rheology modifiers are also compounds that provide "structure" to the compositions to prevent settling out (separation) of insoluble and partially soluble components. By increasing the viscosity at process temperatures, the rheology modifiers will increase the viscosity above 200 centipoise. However, the rheology modifiers are thixotropic in behavior and, therefore, their viscosity decreases as shear and pressure increases. Consequently, when the rheology modifiers are used in the compositions of the invention, they maintain the suspension of insoluble and partially soluble components. This capability can be particularly important if, during processing, the composition must be left stagnant in process lines and hoses. The rheology modifiers will maintain the suspension of the insoluble and partially soluble components for a period of time that depends on the viscosity of the composition and on the amount of rheology modifier present. The thixotropic behavior of the rheology modifiers causes their viscosity to drop when processing is resumed and the composition is no longer stagnant due to the application of pressure and shear forces. In addition to stabilizing the suspension of insoluble and partially soluble components, the rheology modifiers of the invention also help to stabilize the compositions on the bodyfacing or other materials to which the compositions are applied. Examples of suitable rheology modifiers include silica, silica silylate, silica methyl silylate, quaternary starch compounds and mixtures thereof. Such rheology modifiers can help maintain the suspension of an insoluble or partially soluble emollient, such as a siloxane, within the composition. The compositions of the invention can include from about 0.5 to about 5 percent by weight of one or more rheology modifiers.

The stability of the compositions of the invention can also be improved through the use of one or more alkyl silicones as one of the solidifying agents or emollients in the composition. Alkyl silicones have been found to facilitate the homogenous incorporation of some emollients, such as siloxanes, into the hydrocarbon-based compositions of the invention. The ability of alkyl silicones to stabilize siloxanes was unexpected given the inherent incompatibility of siloxanes with oils such as may be used in the compositions of the invention. The inherently high molecular weights of alkyl silicones are believed to be a factor in their role as solidifying agents. Additionally, the alkyl silicones are believed to act as coupling agents for the siloxanes with the organic phase of the composition which may

include fats/oils, waxes or petrolatum. The alkyl silicones are able to maintain the homogeneity of the siloxanes in the compositions even at higher temperatures, such as may be experienced during processing. Therefore, in order to perform the desired "coupling" effect, the character of the alkyl silicone (alkylmethylsiloxane) must be balanced as described previously herein. The compositions of the invention can include from about 0.5 to about 30 percent by weight of one or more siloxanes, such as dimethicone. Additionally, the compositions of the invention can include from about 0.5 to about 30 percent by weight of one or more alkyl silicones.

Compositions of the invention containing alkyl silicones have very good phase stability at high process temperatures. An example of such a composition containing 2% by weight of dimethicone and 1% by weight of alkyl silicone is described as Formula 6 in Table 3. herein. A composition such as Formula 6 will maintain the homogeneity of the dimethicone at 85°C for 6 hours. In contrast, a similar composition without alkyl silicone will display complete phase separation of the dimethicone in less than 1 hour at 85°C. Because compositions of the invention can be processed at higher temperatures, the phase stability of dimethicone afforded by the alkyl silicone permits commercial processing of such compositions that was previously unattainable.

If it is desired that the composition provide a treatment for the skin, the composition can also include an active ingredient such as a diaper rash skin protectant. Skin protectants are drug products that protect injured or exposed skin or mucous membrane surface from harmful or annoying stimuli. Suitable active ingredients, in addition to those mentioned above as suitable emollients, that can be incorporated into the composition include, but are not limited to, allantoin and its derivatives, aluminum hydroxide gel, calamine, cocoa butter, dimethicone, cod liver oil, glycerin, kaolin and its derivatives, lanolin and its derivatives, mineral oil, petrolatum, shark liver oil, talc, topical starch, zinc acetate, zinc carbonate, zinc oxide and the like, and mixtures thereof. The composition may include from about 0.10 to about 95 percent by weight of the active ingredient depending upon the skin protectant, the amount desired to be transferred to the skin or the amount of a particular skin protectant required in the U.S. Food and Drug Administration monograph.

In order to better enhance the benefits to the wearer, additional ingredients can be included in the compositions of the present invention. For example, the classes of ingredients that may be used and their corresponding benefits include, without limitation: antifoaming agents (reduce the tendency of foaming during processing); antimicrobial actives; antifungal actives; antiseptic actives; antioxidants (product integrity); antioxidants-cosmetic (reduce oxidation); astringents-cosmetic (induce a tightening or tingling

sensation on skin); astringent-drug (a drug product that checks oozing, discharge, or bleeding when applied to skin or mucous membrane and works by coagulating protein); biological additives (enhance the performance or consumer appeal of the product); colorants (impart color to the product); deodorants (reduce or eliminate unpleasant odor and protect against the formation of malodor on body surfaces); other emollients (help to maintain the soft, smooth, and pliable appearance of the skin by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin's appearance); external analgesics (a topically applied drug that has a topical analgesic, anesthetic, or antipruritic effect by depressing cutaneous sensory receptors, or that has a topical counterirritant effect by stimulating cutaneous sensory receptors); film formers (to hold active ingredients on the skin by producing a continuous film on skin upon drying); fragrances (consumer appeal); silicones/organomodified silicones (protection, tissue water resistance, lubricity, tissue softness); oils (mineral, vegetable, and animal); natural moisturizing agents (NMF) and other skin moisturizing ingredients known in the art; opacifiers (reduce the clarity or transparent appearance of the product); powders (enhance lubricity, oil adsorption, provide skin protection, astringency, opacity, etc.); skin conditioning agents; solvents (liquids employed to dissolve components found useful in the cosmetics or drugs); and surfactants (as cleansing agents, emulsifying agents, solubilizing agents, and suspending agents).

20 An important property of the compositions of the different aspects of the present invention is their ability to remain on the surface of the bodyside liner 22 and their resistance to migration into the diaper 10 such that they can readily be transferred to the wearer's skin. In this regard, the articles having the compositions of the present invention applied to their bodyside liner 22 define a z-direction migration loss of no more than about 25 55%, desirably no more than about 50%, more desirably no more than about 45%, even more desirably no more than about 40% and yet even more desirably no more than about 35% when subjected to the Z-Direction Lotion Migration Test set forth below. In articles that have a greater z-direction migration loss, the composition undesirably migrates into the interior and along the surface of the bodyside liner 22 and at times through the 30 bodyside liner 22 into the absorbent body 24 of the article which results in a lower reduction in abrasion and less transfer to the skin of the wearer.

Another important measure of the compositions of the different aspects of the present invention is their ability to resist migration laterally along the surface of the bodyside liner 22. In this regard, the articles having the compositions of the present 35 invention applied to the bodyside liner 22 define a cd-direction migration loss of no more than about 40%, desirably no more than about 35%, more desirably no more than about



30%, even more desirably no more than about 25% and yet even more desirably no more than about 20% when subjected to the CD-Direction Lotion Migration Test set forth below. In articles which have a greater cd-direction migration loss, the composition undesirably migrates along the surface of the bodyside liner 22 and at times through the bodyside liner 22 into the absorbent body 24 of the article which results in a lower reduction in abrasion and less transfer to the skin of the wearer.

Moreover, to provide the improved stability and transfer to the skin of the wearer, the compositions of the present invention may define a melting point of from about 32°C to about 100°C, desirably from about 35°C to about 80°C, and more desirably from about 40°C to about 75°C. Compositions that have lower melting points exhibit migration of the composition during use and at elevated temperatures in storage that can undesirably result in reduced transfer to the skin. Whereas, compositions that have higher melting points may require that the composition be at a temperature above the flash point of the bodyside liner 22 material which can undesirably lead to fires. The melting points of the compositions of the invention cause the compositions to be relatively immobile and localized on the bodyfacing surface 11 of the diaper 10 at room temperature and readily transferable to the skin of the wearer at body temperatures. However, the compositions of the invention are not completely liquid under extreme storage conditions. Desirably, the compositions are easily transferable to the skin by way of normal contact, wearer motion, adhesion or body heat. When the compositions are relatively immobilized at room temperature, a lesser quantity of composition is required on the bodyfacing surface 11 to provide a beneficial effect.

The composition of the present invention may further define a viscosity at about 54.5°C of from about 200 to about 1,000,000 centipoise, desirably from about 50,000 to about 800,000 centipoise, and more desirably from about 100,000 to about 500,000 centipoise for reduced migration and improved transfer to the skin of the wearer. Compositions that have lower melt point viscosities exhibit migration of the composition through the bodyside liner 22 into the absorbent body 24 of the article which can undesirably result in reduced transfer to the skin. Whereas, compositions that have higher melt point viscosities may be so solid as to also exhibit a reduced transfer to the skin.

Further, to provide the improved stability and transfer to the skin of the wearer, the compositions of the present invention may also define a viscosity of from about 50 to about 10,000 centipoise, desirably from about 100 to about 500 centipoise, and more desirably from about 150 to about 250 centipoise at a temperature of 60°C.

The penetration hardness of the compositions of this invention can be from about 5 to about 365 millimeters, more desirably from about 10 to about 300 millimeters, more

desirably from about 20 to about 200 millimeters, and still more desirably from about 40 to about 120 millimeters at 25°C. (Compositions having a needle penetration hardness greater than 365 millimeters cannot be measured using ASTM method D 1321). The hardness of the compositions of this invention is important for two reasons. First, the softer the formulation the more mobile the formulation will be, making the formulation more likely to migrate to the inner plies of the diaper 10, which is not desirable. Secondly, softer compositions tend to be more greasy/oily to the touch, which is also less desirable. In general, compositions having a needle penetration hardness of from about 200 to about 365 millimeters feel creamy to slightly greasy with less smoothness (depending on additives). Compositions that have needle penetration hardness values of from about 5 to about 200 millimeters feel silky to creamy and very smooth (depending on additives).

The composition may be applied to the entire bodyfacing surface 11 of the bodyside liner 22 or may be selectively applied to particular sections of the bodyfacing surface 11, such as the medial section along the longitudinal centerline of the diaper 10, to provide greater lubricity of such sections and to transfer such composition to the wearer's skin. Alternatively, the bodyfacing surface 11 of the bodyside liner 22 may include multiple stripes of the composition applied thereto as illustrated in Fig. 3. For example, the bodyfacing surface 11 of the bodyside liner 22 may include from 1 to 20 stripes 54 of composition extending along the longitudinal direction of the diaper 10. The stripes 54 may extend the full length of the bodyside liner 22 or only a portion thereof. The stripes 54 may also define a width of from about 0.2 to about 1 centimeters.

The composition should cover a sufficient amount of the bodyfacing surface 11 of the bodyside liner 22 to ensure adequate transfer to the skin and reduced abrasion between the bodyside liner 22 and the wearer's skin. Desirably, the composition is applied to at least about 5 percent and more desirably at least about 25 percent of the bodyfacing surface 11 of the bodyside liner 22.

The composition can be applied to the bodyside liner 22 at any add-on level that provides the desired transfer benefit. For example, the total add-on level of the composition can be from about 0.05 to about 100 mg/cm<sup>2</sup>, desirably from about 1 to about 50 mg/cm<sup>2</sup> and more desirably from about 10 to about 40 mg/cm<sup>2</sup> for improved performance. The add-on amount will depend upon the desired effect of the composition on the skin barrier function and the specific composition. As discussed above, the improved stability and reduced tendency to migrate of the compositions of the present invention allows a lesser amount of composition to be applied to the bodyside liner 22 to achieve the same benefit when compared with conventional compositions.

The composition may be applied to the bodyside liner 22 in any of many well known manners. A preferred method to uniformly apply the composition to the bodyfacing surface 11 of the bodyside liner 22 is spraying or slot coating. Spraying or slot coating the composition is the most exact process and offers maximum control of the composition distribution and transfer rate. However, other methods, such as roto-gravure or flexographic printing and foam application can be used. The compositions of the present invention can be applied after the bodyfacing material has been incorporated into the absorbent article or prior to incorporating the body facing material into the absorbent article.

The composition may be applied to the bodyside liner 22 by (a) heating the composition to a temperature above the melting point of the composition, causing the composition to melt, (b) uniformly applying the melted composition to the bodyfacing surface 11 of the bodyside liner 22; and (c) resolidifying the composition applied to the bodyfacing surface 11. Desirably, resolidification of the composition occurs almost instantaneously, without the need for external cooling devices such as chill rolls. This can occur if the composition is heated to a temperature only slightly above or at the melting point of the composition. However, external cooling devices such as chill rolls, either before or after the application of melt, can be used if desired to accelerate resolidification. Other cooling methods such as cooling tunnels could also be used.

The increased viscosity of the composition at the process temperature and the instantaneous resolidification tends to impede penetration of the composition into the bodyside liner 22 and absorbent body 24 of the diaper 10 and retain it on the bodyfacing surface 11 of the bodyside liner 22, which is advantageous. For example, the temperature of the melted composition can advantageously be less than about 10°C, more desirably less than about 5°C, and still more desirably less than about 2°C above the melting point of the composition prior to applying it to the bodyside liner 22 for reduced migration. As the temperature of the melted composition approaches the freezing point of the composition, the viscosity of the melted composition generally increases, which further enhances the tendency of the melted composition to be retained on the bodyfacing surface 11.

The present invention is also directed to an absorbent article, such as a diaper 10, that includes an outer cover 20, a liquid permeable bodyside liner 22, an absorbent body 24 and a composition. The bodyside liner 22 defines a bodyfacing surface 11. As already described herein, the bodyfacing surface 11 is that portion of the article that comes into contact with the skin of the wearer or user of the article. When the article is a diaper 10, the bodyfacing surface 11 typically is primarily the bodyside liner 22, but the bodyfacing

surface 11 can also include waist and leg elastics 26, 28, containment flaps and fasteners 30. When the article is a primarily two-dimensional substrate such as a tissue or wet wipe, the entire surface area of the tissue or wet wipe is the bodyfacing surface 11 as any portion of such articles may contact the user's skin.

5           The bodyside liner 22 is in superposed relation to the outer cover 20. The absorbent body 24 is located between the bodyside liner 22 and the outer cover 20. At least a portion of the bodyfacing surface 11 of the bodyside liner 22 has a composition on it. The composition includes from about 0.5 to about 75 percent by weight of natural fats or oils. The natural fats and oils can be selected from avocado oil, borage oil, sunflower  
10 oil, soybean oil, corn oil, cottonseed oil and mixtures of these compounds. The composition also includes from about 0.5 to about 5 percent by weight of sterols or sterol derivatives. The sterols and sterol derivatives can be selected from cholesterol, sitosterol, stigmasterol, tall oil sterol, soy sterol and mixtures of these compounds. Additionally, the composition includes from about 20 to about 75 percent by weight of one or more  
15 emollients. The emollients can be selected from petrolatum, silicone oils, dimethicone, lanolin and mixtures of these compounds. The composition further includes from about 25 to about 75 percent by weight of one or more solidifying agents. The solidifying agents may be selected from cerasin, microcrystalline wax, ozokerite, alkylmethylsiloxanes including alkyl silicones and mixtures of these compounds. The composition also includes  
20 from about 5 to about 20 percent by weight of one or more viscosity enhancers. The viscosity enhancers can be selected from ethylene/vinyl acetate copolymers, polyethylene, silica and mixtures of these compounds.

          The composition has physical properties that are suitable to provide a relative degree of immobilization on the bodyfacing surface 11 at room temperature and to provide  
25 sufficient fluid or transfer properties at body temperature so that the composition can migrate to the skin. Typically, the composition has a melting point of from about 32°C to about 100°C and a viscosity of from about 10 to about 10,000 centipoise at a temperature of about 60°C. The composition has a viscosity of from about 200 to about 100,000 at about 55°C. The composition may also have a penetration hardness of from about 5  
30 millimeters to about 365 millimeters at 25°C. The composition is typically present on the bodyfacing surface 11 in an amount of from about 0.1 g/m<sup>2</sup> to about 30 g/m<sup>2</sup>. The composition applied to the bodyfacing surface 11 may have additional ingredients added to it in order to provide additional benefits or to enhance the functionality and processability of the composition.

35           The present invention is also directed to a method of applying a composition to a bodyfacing surface 11 of a bodyside liner 22 of an absorbent article. The method includes

a step of heating a composition to a temperature above the melting point of the composition. The composition generally enhances the skin barrier function and can include a natural fat or oil, a sterol or sterol derivative, an emollient, a solidifying agent, and a viscosity enhancer. The melting point of the composition is from about 32°C to about 100°C. The method also includes a step of applying the composition to the bodyfacing surface 11 of a bodyside liner 22 of an absorbent article. The method further includes a step of resolidifying the composition. The composition can be applied to the bodyfacing surface 11 using any of the techniques already describe herein such as foam application, spraying, slot coating and printing. The composition can be resolidified using devices that are commonly used for cooling, such as chill rolls and cooling tunnels, or the composition can be resolidified by selecting a combination of ingredients that puts the melting point close to the processing temperature. When the melting point of the composition is close to the processing temperature, the composition should quickly resolidify after application to the bodyfacing surface 11. Typically, after resolidification, the composition has a viscosity of greater than about 200 centipoise and a penetration hardness of from about 5 to about 365 millimeters at 25°C.

The present invention is further directed to a method for enhancing the barrier function of the skin. The method includes a step of contacting a skin surface of a user of an absorbent article with a bodyfacing surface 11 of a bodyside liner material. The method could also include a step of contacting the skin surface of a user of a tissue or wet wipe article with the outer surface of the material from which the tissue or wet wipe is constructed. The bodyfacing surface 11 or outer surface has a composition on it. The composition can include a natural fat or oil, a sterol or sterol derivative, an emollient, a solidifying agent and a viscosity enhancer. The relative amounts and combinations of composition components can be varied. The method of the invention also includes a step of maintaining the bodyfacing surface 11 in contact with the skin surface of the user for a sufficient amount of time to transfer the composition to the skin surface. The amount of time is related to the nature of the composition and its physical properties; different compositions will transfer to a skin surface at different rates. The method further includes a step of repeating the maintaining step for a sufficient period of time to evidence enhancement of skin barrier function. Therefore, the method includes repeating the contact of the skin surface with the bodyfacing surface 11 of the liner material.

As suggested by the compositions already described herein, the composition applied to the bodyfacing surface 11 can include from about 0.1 to about 95 percent by weight of one or more natural fats and oils, from about 0.1 to about 10 percent by weight of one or more sterols or sterol derivatives, from about 1 to about 95 percent by weight of

one or more emollients, from about 5 to about 95 percent by weight of one or more solidifying agents and from about 1 to about 25 percent by weight of one or more viscosity enhancers. Examples of suitable fats and oils, sterols and sterol derivatives, emollients, solidifying agents and viscosity enhancers are as described herein.

- 5           The descriptions of the articles and compositions of the invention provided herein have included references to various tests for assessing the attributes or properties of the components of the articles and compositions as well as the articles and compositions in their entireties. Descriptions of the test procedures used to make those assessments are now provided.

10

#### Hydrostatic Pressure Test

- The Hydrostatic Pressure Test is a measure of the liquid barrier properties of a material. In general, the Hydrostatic Pressure Test determines the height of water (in centimeters) in a column that the material will support before a predetermined amount of water passes  
15       through. A material with a higher hydrohead value indicates it is a greater barrier to liquid penetration than a material having a lower hydrohead value. The Hydrostatic Pressure Test is performed according to Method 5514 - Federal Test Methods Standard No. 191A.

#### Frazier Porosity Test

- 20       The Frazier Porosity values referred to in the present specification can be determined employing a Frazier Air Permeability Tester (Frazier Precision Instrument Co., Gaithersburg, Maryland) and Method 5450, Federal Test Methods Standard No. 191A. For the purposes of the present invention, the test is conducted with a sample that measures 8 inches x 8 inches.

25

#### Water Vapor Transmission Test

- A suitable technique for determining the WVTR (water vapor transmission rate) value of a material is as follows. For the purposes of the present invention, 3-inch diameter (76 millimeter) circular samples are cut from the test material and from a control material,  
30       CELGUARD 2500 material (Hoechst Celanese Corporation). Two or three samples are prepared for each material. Test cups used for testing are cast aluminum, flanged, 2 inches deep and come with a mechanical seal and neoprene gasket. The cups are distributed by Thwing-Albert Instrument Company, Philadelphia, Pennsylvania, under the designation "Vapometer cup #681". One hundred milliliters of distilled water are poured  
35       into each Vapometer cup, and each of the individual samples of the test materials and control material are placed across the open top area of an individual cup. Screw-on

flanges are tightened to form a seal along the edges of the cups leaving the associated test material or control material exposed to the ambient atmosphere over a 62 millimeter diameter circular area (an open, exposed area of about 30 cm<sup>2</sup>). The cups are then weighed, placed on a tray, and set in a forced air oven set at 100°F (38°C). The oven is a constant temperature oven with external air circulating through it to prevent water vapor accumulation inside. A suitable forced air oven is, for example, a Blue M Power-O-Matic 60 oven distributed by Blue M Electric Co. of Blue Island, Illinois. After 24 hours, the cups are removed from the oven and weighed. The preliminary, test WVTR value is calculated as follows:

$$\text{Test WVTR} = \frac{[(\text{grams weight loss over 24 hours}) \times 7571]}{24} \quad (\text{g/m}^2/24 \text{ hours})$$

The relative humidity within the oven is not specifically controlled. Under predetermined set conditions of 100°F and ambient relative humidity, the WVTR for CELGUARD 2500 materials has been determined to be 5000 g/m<sup>2</sup>/24 hours. Accordingly, CELGUARD 2500 material is run as a control sample with each test. CELGUARD 2500 material is a 0.0025 cm thick film composed of a microporous polypropylene.

#### Z-Direction Composition Migration Test

This test determines the quantity of composition that remains on the target area of the bodyfacing surface of an absorbent article after a given period of time at a given temperature. Specifically, the purpose of the test is to compare the amount of composition present in the target zone on articles stored at a lower temperature with that present on articles stored at a higher temperature. The test simulates storage at elevated temperature conditions to which absorbent articles may be subjected. For example, such articles may be stored in the trunk of a vehicle or in a warehouse in a warm climate such as in a warehouse in Arizona in July or August. The z-direction migration loss is a measure of the composition migration after storage at 130°F when compared to the composition migration at 73°F after a fixed period of time. Thus, this test predicts the amount of composition that will be available on the bodyfacing surface of the article for transfer to the skin when the article is used as well as how quickly it will undesirably migrate away from or along the bodyfacing surface of the article in use.

Specifically, the test is conducted as follows:

1. Ten (10) products having a composition applied to the topsheet or bodyside liner are obtained.
2. Five (5) products are placed in a controlled environment at a temperature of 73°F and a relative humidity of 50% for a fixed period of time such as, for example, 28 days. The other five (5) products are placed in a controlled environment at a temperature of 130°F and ambient humidity for the same period of time.
3. The products are removed from the controlled environment and a sample of the bodyside liner having a width of 3.75 inches and a length of 13 inches is removed from the center of each product.
4. The samples are then subjected to Soxhlet Extraction with Gravimetric Analysis (SEGA) as follows. The test apparatus includes a reboiler, chloroform vapor duct, cold water condenser, holding tank where the samples are placed and a chloroform recycle duct. The components of the test apparatus are conventional glassware well known to those skilled in the art. For example, the reboiler may include a 250 ml round bottom flask and the vapor duct can include an 85 ml soxhlet. A sample is placed in the holding tank and subjected to chloroform washing cycles for 2.5 hours. One hundred twenty-five milliliters of liquid chloroform is placed in the reboiler. The chloroform vaporizes and rises up through the vapor duct into the condenser having tap water therein that, in turn, causes the chloroform to liquefy and fall into the holding tank with the sample. The chloroform dissolves the composition from the liner sample. When the liquid chloroform reaches a high enough level, the recycle duct returns the chloroform/composition mixture to the reboiler. The temperature in the reboiler is controlled such that it is above the boiling point of the chloroform but below that of the composition such that only the chloroform vaporizes to start the process over again. One complete wash cycle takes approximately 15 minutes with about 75 milliliters of chloroform circulating through the liner sample in each cycle. Upon completion, the chloroform in the evaporator is evaporated utilizing a conventional vacuum evaporator such as a rotovap commercially available under the model number Buchi 011 RE 121 for a period of 4 minutes followed by placing the composition in an aluminum pan and heating on a hot plate with forced air circulation for an additional 30 minutes.

35



5. The residue (composition) remaining for each sample is then weighed. The amount of composition recovered from the products stored at 73°F is then compared to the amount of composition recovered from the products stored at 130°F to determine the stability of the composition formulation at high temperature.

5

The z-direction migration loss of the absorbent article is then determined as follows:

$$\text{Z-direction migration loss (\%)} = [(L_{73} - L_{130})/L_{73}] \times 100$$

10 wherein,

$L_{73}$  = average weight (g) of composition recovered per sample stored at 73°F

$L_{130}$  = average weight (g) of composition recovered per sample stored at 130°F

15 CD-Direction Composition Migration Test

This test determines the quantity of composition that remains on the specific location where it is applied on the bodyfacing surface of an absorbent article after a given period of time at a given temperature. Specifically, the purpose of the test is to compare the amount of composition present in the applied location on the topsheet or bodyside liner with that present on the remaining portions of the bodyside liners of the articles after being stored at an elevated temperature. The test simulates storage at elevated temperature conditions to which absorbent articles may be subjected. For example, such articles may be stored in the trunk of a vehicle or in a warehouse in a warm climate such as in a warehouse in Arizona in July or August. The cd-direction migration loss is a measure of the lateral composition migration along the bodyfacing surface of the article after storage at 130°F after a fixed period of time. Thus, this test predicts the amount of composition that will be available in the desired location on the bodyfacing surface of the article for transfer to the skin when the article is used as well as how quickly it will undesirably migrate away from or along the bodyfacing surface of the article in use.

30

Specifically, the test is conducted as follows:

1. Five (5) products having a composition applied to the bodyside liner in a specific pattern are obtained.

35

2. The products are placed in a controlled environment at a temperature of 130°F and ambient humidity for a fixed period of time such as, for example, 28 days.
3. The products are removed from the controlled environment and the bodyside liner on each product is removed and dissected to remove the portion of the bodyside liner to which the composition was actually applied. For example, if the composition was applied as 4 continuous lines having a width of 0.25 inches with spaces of 0.75 inches in between, the 4 strips of bodyside liner would be removed.
4. The samples which include the portions of the bodyside liner to which the composition was applied are then grouped together and subjected to Soxhlet Extraction with Gravimetric Analysis (SEGA) as described above. The remaining portions of the bodyside liner are also grouped together and subjected to a separate SEGA extraction.
5. The residue (composition) remaining for each group is then weighed. The amount of composition recovered from the portions of the bodyside liner to which the composition was applied is then compared to the amount of composition recovered from the remaining portions of the bodyside liner to determine the stability of the composition at high temperature.
- The cd-direction migration loss of the absorbent article is then determined as follows:

$$\text{CD-direction migration loss (\%)} = [L_{sp} / (L_a + L_{sp})] \times 100$$

wherein,

$L_{sp}$  = average weight (g) of composition recovered from the portions of the bodyside liner to which the composition was not applied per diaper

$L_a$  = average weight (g) of composition recovered from the portions of the bodyside liner to which the composition was applied per diaper

Barrier Recovery Test

Recovery of skin barrier function can be measured by first causing damage to the skin (thereby irritating the skin barrier) and by then measuring the Transepidermal Water Loss ("TEWL") associated with the compromised skin over a length of time following  
5 inducement of the irritation. The test is conducted on adult females who have not used lotions or ointments on the skin and have not bathed within 2 hours prior to the test. Each test participant has four test sites on each of their forearms: one control and three experimental on each forearm. The test code sites and control site are randomized.

Each test site (1.25in x 1.25 in) is marked with a surgical marker. A preliminary  
10 TEWL measurement is taken after an initial IVORY soap wash and a wait period of approximately 20 minutes. TEWL is measured on each test site and on the control site to establish the initial TEWL value of each site on the forearms. The preliminary TEWL measurement must measure less than 10 g/m<sup>2</sup>/hour before initiation of the test procedure.

The TEWL measurements are taken with an evaporimeter, such as the  
15 DERMALAB instrument manufactured by Cortex Technology. Each test measurement is taken over a period of one minute. The initial 30 seconds (a total of 30 TEWL values) are included for the probe to reach a stabilized measure before collection of the TEWL values. The final 30 second TEWL values are collected. TEWL values are taken once per second (a total of 30 TEWL values). The digital output from the DERMALAB instrument gives the  
20 rate of trans-evaporative water loss (TEWL) in g/m<sup>2</sup>/hr.

The value reported for the mean TEWL measure for each test code (grams/m<sup>2</sup> in one hour) is the arithmetic mean for all subjects, taken at the appropriate test site. A separate mean net TEWL measure is determined for each test code and for the control site.

Each site is then abraded to achieve a change in TEWL of approximately 10  
25 g/m<sup>2</sup>/hr. The abrasion can be performed using a piece of fine coarse sandpaper or a similar material. Next, there is a fifteen-minute waiting period before a post-abrasion TEWL measurement is taken of each site. Each subject tests three test codes during each test session plus a control site. Twenty microliters of test composition are then  
30 applied to each of the experimental (but not the control) sites. The test composition is spread on the site by hand. TEWL measurements are then taken at 1, 2 and 4 hours after the application of the test composition.

The compositions of the present invention can be further described through examples of compositions considered to be within the scope of the present invention. The  
35 examples provided herein are intended to be representative of the present invention but are not intended to delineate the extent of the present invention. To the extent that amounts of

individual components or total compositions are referred to in terms of "effective amounts", "effective amount" is understood to mean an amount that will have the desired effect of that component or composition. For example, an "effective amount" of one of the compositions of the invention is understood to mean an amount that, when applied to the bodyfacing or skin contacting surface of an article, will enhance the barrier function of the skin. Illustrative examples of the compositions of the invention are provided in Table 2. below.

TABLE 2

Formula (weight percent)	1	2	3	4
Petrolatum	58.50%	53%	11.50%	--
Octyl Dodecanol	--	--	5%	--
Stearyl Dimethicone	--	--	--	15%
Myristyl myristate	--	--	--	5%
Sunflower Oil	5%	15%	--	--
Borage Oil	--	--	30%	--
Avocado Oil	--	--	--	5%
Lanolin	--	--	--	5%
Linoleic Acid	--	--	--	0.50%
Palmitic Acid	--	--	--	0.50%
Soy Sterol	0.50%	4%	10%	--
Cholesterol	--	--	--	2%
PROLIPID 141 blend	--	3%	--	--
Dimethicone 12,500 cSt	--	2%	5%	2%
Ozokerite Wax	20%	15%	--	--
Hydrogenated Cottonseed Oil	--	--	--	50%
Cetyl Esters	10%	--	--	5%
C30-C45 Alkyl Dimethicone	--	1%	30%	--
Ethylene Vinyl Acetate Copolymer	5%	5%	7.50%	3%
Silica	1%	2%	--	4%
Silica Methyl Silylate	--	--	1%	3%
Formula (weight percent)	5	6	7	8
Petrolatum	43%	39%	20%	--
Octyl Dodecanol	10%	--	--	--
C12-C15 Alkyl Benzoate	10%	--	3%	--
Phenyl Trimethicone	--	5%	--	--
Cetyl Palmitate	--	--	--	7%
Mineral Oil	--	--	10.75%	--
Sunflower Oil	--	--	15%	--
Borage Oil	--	5%	--	--
Avocado Oil	2%	--	--	10%
Lanolin	--	1%	--	30%
Linoleic Acid	1%	--	--	--
Palmitic Acid	1%	--	--	--
Soy Sterol	--	--	7%	--
Cholesterol	--	3%	--	--
Lanosterol	3%	--	--	10%
Dimethicone 12,500 cSt	--	2%	--	--
Ozokerite Wax	--	--	5%	--
Microcrystalline Wax	--	22%	10%	10%
Hydrogenated Cottonseed Oil	--	--	10%	15%
Cetyl Esters	10%	--	5%	5%
Paraffin Wax	--	--	5%	--
C30-C45 Alkyl Dimethicone	--	--	2%	--
C20-C22 Alkyl Dimethicone	--	6%	--	--
Ethylene Vinyl Acetate Copolymer	15%	5%	6.25%	10%
Silica	--	--	--	3%
Silica Methyl Silylate	5%	2%	1%	--
Zinc Oxide	--	10%	--	--

As used herein, all recited ranges of amounts, temperatures, molecular weights and penetration hardnesses are intended to include all sub-ranges within the recited ranges, even though not specifically stated.

The following examples are presented to provide a more detailed understanding of the invention. The particular materials and parameters are exemplary and are not intended to limit the scope of the invention. Various compositions representing the compositions of the invention were prepared. The compositions were then evaluated for their ability to enhance the skin barrier function. Formulas 1-10 were prepared as described in Table 3.

Table 3.

Formula (weight percent)	1	2	3	4	5
Petrolatum	43.20%	48.20%	95.00%	83.20%	77.70%
Sunflower Oil	10.00%	10.00%	--	10.00%	10.00%
Glycerin	5.00%	--	--	--	5.00%
PROLIPID 141 blend	1.00%	1.00%	--	1.00%	1.00%
Soy Sterol	0.80%	0.80%	--	0.80%	0.80%
Ozokerite wax	40.00%	40.00%	5.00%	5.00%	5.00%
Sorbitan monooleate	--	--	--	--	0.50%
Dimethicone	--	--	--	--	--
Alkyl Silicone Wax	--	--	--	--	--
	100.00%	100.00%	100.00%	100.00%	100.00%
Formula (weight percent)	6	7	8	9	10
Petrolatum	80.20%	74.70%	43.50%	42.70%	42.00%
Sunflower Oil	10.00%	10.00%	10.00%	10.00%	10.00%
Glycerin	--	5.00%	5.00%	5.00%	5.00%
PROLIPID 141 blend	1.00%	1.00%	1.00%	1.00%	1.00%
Soy Sterol	0.80%	0.80%	0.50%	0.80%	0.80%
Ozokerite wax	5.00%	5.00%	40.00%	40.00%	37.70%
Sorbitan monooleate	--	0.50%	--	0.50%	0.50%
Dimethicone	2.00%	2.00%	--	--	2.00%
Alkyl Silicone Wax	1.00%	1.00%	--	--	1.00%
	100.00%	100.00%	100.00%	100.00%	100.00%

PROLIPID 141 blend is available from International Specialty Products of Wayne, New Jersey. Ozokerite wax as used in Table 3. is a blend of microcrystalline wax (58% by weight), ELVAX resin (15% by weight), paraffin wax (10% by weight), cetyl esters (10% by weight) and mineral oil (7% by weight); the blend is available from International Group, Inc. of Toronto, Canada.

### Barrier Recovery Test

The benefits provided by the compositions of the invention to the skin barrier are demonstrated by measuring the Transepidermal Water Loss ("TEWL") associated with areas of the skin to which the compositions have been applied and comparing them with the TEWL of untreated skin surfaces. The general procedure for measuring TEWL is as described previously herein. The present TEWL values were measured in a temperature and humidity controlled room where the temperature was  $71^{\circ} \pm 5^{\circ}\text{F}$  and the relative humidity was  $40\% \pm 5\%$ . For this study, the volar forearm of 16 panelists was abraded by an emery cloth to increase TEWL levels to 16-18 g/m<sup>2</sup>h. After abrasion, twenty microliters of a test formula (Formula 1 or Formula 2, both described in Table 2.) were topically applied to the volar forearm. TEWL measurements were made using a Cortex Technologies DERMALAB evaporimeter instrument after 1, 2 and 4 hours in both the area treated with test formula and in an untreated area. Mean TEWL values are expressed in Table 4. Repeated measures ANOVA analysis was used to adjust for the repeated TEWL measures.

**Table 4.**

Site	PIR Mean	1 Hour Mean	2 Hour Mean	4 Hour Mean
Formula 1	16.6	6.9*	6.1*	6.5*
Formula 2	16.4	4.8*	5.5*	6.0*
Untreated Site	17.3	14.4	13.2	12.7

"\*" denotes statistically significantly different result compared to Untreated Site

"PIR" mean refers to the mean TEWL measurement "post irritation". Skin surfaces treated with a composition of the invention have a reduced level of transepidermal water loss compared with skin surfaces that are not treated with a composition of the invention. In fact, treatment of the skin with the compositions of the invention results in a TEWL measurement approximately equivalent to the skin's TEWL before irritation. Further, Formula 2, without glycerin (a humectant), performed at least as well, if not better, than Formula 1 with glycerin. Reduced TEWL is indicative of the compositions of the invention enhancing the barrier function of the skin.

### Barrier Function (Dye Uptake Test)

Another approach to measuring the barrier function of skin is to measure how well the skin prevents uptake of a water-soluble "insult". A benign water-soluble "insult" can be used to simulate the waste fluid insults experienced by skin that is covered by an

absorbent article. In this case, a water-soluble dye was used as the "insult" fluid to study how well compositions of the invention improve the barrier function of the skin.

The studies were conducted in a temperature and humidity controlled room where the temperature was  $71^{\circ} \pm 5^{\circ}\text{F}$  and the relative humidity was  $40\% \pm 5\%$ . Prior to the start of the study, the volar forearms of 14 panelists were washed to remove any endogenous surface oils. The washing including lathering each panelist's arm with IVORY soap for 30 seconds. The lather was allowed to remain on the panelist's arm for 90 seconds before a thorough rinsing. The panelist's arm was then patted dry. Prior to the application of the test compositions, there was a 20 minute waiting period. After the waiting period, 3 microliters of each test composition were applied at different sites on each panelist's arm.

After a fifteen minute wait period, baseline chromameter readings were taken of each site on the panelists' arms. A MINOLTA chromameter was used to take the readings. The treated sites were then challenged with a water-soluble dye solution containing 3% of FD&C Blue #1 by adding 300 microliters of the dye solution to a HILLTOP chamber. A chamber was placed on each of the treated sites and a control site on each arm. The chamber was pressed down gently to ensure contact with the skin. After one minute of contact, the chamber was removed and the panelist's arm was rinsed under water for 30 seconds. The panelist's arm was patted dry and a chromameter reading was obtained for each treated and the control site. The chromameter readings were recorded in terms of the Hunter color values ("L" for luminosity; "a" is for red/green (positive values=red); "b" is for yellow/blue (positive values=yellow)). The "b" values are the most relevant for quantifying uptake in a FD&C Blue #1 dye uptake study. The results are expressed in Table 5. below as the least square of the mean with the baseline readings subtracted out.

Table 5.

Treatment	Chromameter – $\Delta b$ value
Untreated, control site	-14.0
Formula 3	-9.5*
Formula 4	-7.7*
Formula 5	-8.4*
Formula 6	-6.8*, **
Formula 7	-7.3*, **

\* denotes significantly lower dye uptake than the untreated control site.

\*\* denotes significantly lower dye uptake than the site treated with Formula 3.



The results demonstrate that the least of amount of dye was taken up by skin sites that had been treated with Formulas 4, 6 & 7 which represent the compositions of the invention. A lower amount of dye uptake is indicated by a more positive (or less negative)  $\Delta b$  value that represents a lesser degree of blue color intensity. The lowest blue color intensity was measured for a composition that did not contain glycerin (a humectant) but that did contain dimethicone and alkyl silicone. Therefore, compositions of the invention enhance the barrier function of the skin.

An additional set of experiments was conducted to evaluate whether the compositions of the invention provide a beneficial effect on the skin barrier function of the skin. In this series of experiments, the compositions of the invention were applied to a liner material in order to determine whether the compositions remain beneficial when they are transferred to the skin from a liner material.

This set of experiments was conducted in a room with controlled temperature and humidity where the temperature was  $71^{\circ} \pm 5^{\circ}\text{F}$  and the relative humidity was  $40\% \pm 5\%$ . In preparation for the tests, the volar forearms of thirty (30) panelists were washed to remove any endogenous surface oils. The washing procedure included lathering each panelist's arm with IVORY soap for thirty seconds. The lather was kept on the panelist's arm for 90 seconds and was followed by a thorough rinsing. Each panelist's arm was patted dry and there was a twenty minute wait period before baseline measurements for skin TEWL, conductance and chromameter values were taken. This study included four test sites and one control site on each panelist's arm. The test sites were to evaluate the skin barrier effect of (1) untreated liner material; and (2) liner material treated with test formulas (Formulas 2, 8 and 9). The add-on level of treatment was approximately 0.2 grams of Formula/liner.

The baseline skin TEWL (Transepidermal Water Loss) was measured using a DERMALAB evaporimeter instrument and the baseline conductance was measured using a SKICON 200 instrument available from I.B.S. Inc. After the baseline measurements were made, each panelist's arm was wiped with a folded liner. The liner material was a spunbond liner material and the folded size of the material was approximately 4 inches by 2 1/4 inches. The liner material was folded in half lengthwise and wiped across the desired arm site five (5) times, the liner material was opened and then, the liner material was refolded to expose a new surface and again wiped five (5) times across the desired arm site. For the experiments testing the treated liner material, the wipings were done with the treated side of the liner material. Even after refolding of the liner material, the new wiping was always done with a freshly uncovered, treated surface of the liner material. The wiping procedure was repeated every 15 minutes for a total of 30 cycles. After the last

cycle, the skin TEWL, conductance and chromameter values were measured. ANOVA statistical analysis was used to compare the measurements for the two test sites and the control sites. The baseline score was used as a covariate and differences between subjects were adjusted. Therefore, a correction was made to compensate for the differences in "starting points" between subjects. The Protected Least Square Difference method was used for multiple comparisons. The values for skin TEWL and conductance are reported in Table 6. below.

Table 6.

Test Site	Skin TEWL (g/m <sup>2</sup> hr)	Conductance
Untreated, control site	6.20	219.7
Untreated liner material	6.22	232.7
Liner treated with Formula 2	5.83 *	277.6 *
Liner treated with Formula 8	5.76 *	311.4 *
Liner treated with Formula 9	5.65 *	314.2 *

\*denotes statistically different from control site and untreated liner material

The results of this experiment show that compositions of the invention have a beneficial effect on the skin barrier function when the compositions are transferred to the skin from a liner material. The sites tested with treated liners (Formulas 2, 8 & 9) had significantly lower skin TEWL values. These results suggest that the skin sites to which Formulas 2, 8 & 9 had been applied lost less moisture because the skin barrier was functioning better. The conductance values reflect the skin's ability to conduct current and skin having a higher moisture content will have a higher conductance or ability to conduct current. The sites tested with treated liners (Formulas 2, 8 & 9) had a significantly higher conductance, therefore reflecting a higher moisture content. The higher moisture content indicates better skin barrier function.

After measurement of the skin hydration and conductance values, the test sites and control site on each panelist's arm were exposed to water-soluble dye solution to measure how well the skin barrier prevented uptake of the colored solution. The water-soluble dye solution included 0.5% of methylene blue dye. Three hundred microliters of the water-soluble dye solution were added to a HILLTOP chamber. The chamber was placed on each site and pressed down gently to ensure contact with the skin. After 1 minute of contact, the chamber was removed and the site was rinsed under water for 30 seconds. The test and control sites of the arm were blotted dry and MINOLTA chromameter readings were made. The chromameter readings are taken in the form of

the Hunter Color Scale values: L (luminosity); a (red/green value where positive values=red); and b (yellow/blue value where positive values=yellow). The "b" value was the most relevant for evaluating the uptake of methylene blue dye solution. The results are expressed as the least square means for each measure and the data was analyzed using ANOVA statistical analysis for controlling the baseline scale measure and subject differences. The results are provided in Table 7. below.

Table 7.

Treatment	Chromameter – b value
Untreated, control site	-1.7
Untreated liner	-4.8
Liner treated with Formula 2	-0.7 *
Liner treated with Formula 8	-1.2 *
Liner treated with Formula 9	-0.7 *

\*denotes significantly lower dye uptake than the untreated liner

10

The results show that the barrier function of skin is improved when the skin is treated with a liner to which a composition of the invention has been applied. The test sites that had been treated with liner material to which Formulas 2, 8 & 9 had been applied showed the lowest level of dye uptake as indicated by the most positive (or least negative) "b" color value. The reduced level of dye uptake suggests that skin treated with a composition of the invention such as any one of Formulas 2, 8 or 9 would also have a reduced uptake of other water-soluble insults such as bodily wastes. Thus, the compositions of the invention improve the function of the skin barrier. This beneficial effect is particularly important for individuals whose skin must be covered by an absorbent article for the containment of bodily wastes.

20

#### Skin TEWL and Dye Uptake for Dimethicone-Containing Formulas

Formulas with and without the combination of dimethicone/alkyl silicone wax were evaluated for their effect on the skin barrier. Skin barrier effect was evaluated through measurement of skin TEWL and dye uptake.

25

The experiments were conducted in a room with controlled temperature and humidity where the temperature was  $71^{\circ} \pm 5^{\circ}\text{F}$  and the relative humidity was  $40\% \pm 5\%$ . In preparation for the experiments, the volar forearms of twenty (20) panelists were washed to remove any endogenous surface oils. The washing procedure included lathering each panelist's arm with IVORY soap for thirty seconds. The lather was kept on

30

the panelist's arm for 90 seconds and was followed by a thorough rinsing. Each panelist's arm was patted dry and there was a twenty minute wait period before baseline skin TEWL and chromameter measurements were taken. This study included three test sites and one control site on each panelist's arm. The test sites were to evaluate the skin barrier effect of (1) untreated liner material; and (2) liner material treated with test formulas (Formulas 9 and 10). The add-on level of treatment was approximately 0.2 grams of Formula/liner.

The baseline skin TEWL was measured using a DERMALAB evaporimeter instrument. After the baseline measurement were made, each panelist's arm was wiped with a folded liner. The liner material was a spunbond liner material and the folded size of the material was approximately 4 inches by 2 ¼ inches. The liner material was folded in half lengthwise and wiped across the desired arm site five (5) times, the liner material was opened and then, the liner material was refolded to expose a new surface and again wiped five (5) times across the desired arm site. For the experiments testing the treated liner material, the wipings were done with the treated side of the liner material. Even after refolding of the liner material, the new wiping was always done with a freshly uncovered, treated surface of the liner material. The wiping procedure was repeated every 15 minutes for a total of 30 cycles. After the last cycle, the skin TEWL and chromameter values were measured. ANOVA statistical analysis was used to compare the measurements for the three test sites and the control sites. The baseline score was used as a covariate and differences between subjects were adjusted. Therefore, a correction was made to compensate for the differences in "starting points" between subjects. The Protected Least Square Difference method was used for multiple comparisons. The skin TEWL values are provided in Table 8. below.

**Table 8.**

Test Site	Skin TEWL (g/m <sup>2</sup> hr)
Untreated, control site	5.6
Untreated liner material	6.5
Liner treated with Formula 9	5.2 *
Liner treated with Formula 10	4.5 **

\* denotes statistically different from untreated liner material

\*\* denotes statistically different than untreated liner and untreated control site

The results of this experiment show that compositions of the invention have a beneficial effect on the skin barrier function when the compositions are transferred to the skin from a liner material. The sites tested with treated liners (Formulas 9 & 10) had significantly

lower skin TEWL values. Addition of the combination of dimethicone and alkyl silicone wax to the compositions of the invention further improves skin barrier function after repetitive wiping.

After measurement of skin TEWL, the test sites and control site on each panelist's arm were exposed to water-soluble dye solution to measure how well the skin barrier prevented uptake of the colored solution. The water-soluble dye solution included 0.5% of methylene blue dye. Three hundred microliters of the water-soluble dye solution were added to a HILLTOP chamber. The chamber was placed on each site and pressed down gently to ensure contact with the skin. After 1 minute of contact, the chamber was removed and the site was rinsed under water for 30 seconds. The test and control sites of the arm were blotted dry and MINOLTA chromameter readings were made. A control site was included to measure the extent of dye uptake on untreated skin. The chromameter readings are taken in the form of the Hunter Color Scale values: L (luminosity); a (red/green value where positive values=red); and b (yellow/blue value where positive values=yellow). The "b" value was the most relevant for evaluating the uptake of methylene blue dye solution. The results are expressed as the least square means for each measure and the data was analyzed using ANOVA statistical analysis for controlling the baseline scale measure and subject differences. The results are provided in Table 9. below.

**Table 9.**

<b>Treatment</b>	<b>Chromameter – b value</b>
Untreated, control site	-24.9
Untreated liner	-23.8
Liner treated with Formula 9	-16.8 *
Liner treated with Formula 10	-14.1 *, **

\* denotes significantly lower dye uptake than the untreated liner and the control site

\*\* denotes significantly lower dye uptake than the liner treated with Formula 9

The results show that the barrier function of skin is improved when the skin is treated with a liner to which a composition of the invention has been applied. The test sites that had been treated with liner material to which Formulas 9 & 10 had been applied showed significantly lower levels of dye uptake as indicated by the most positive (or least negative) "b" color values. The reduced level of dye uptake suggests that skin treated with a composition of the invention such as Formulas 9 or 10 would also have a reduced uptake of other water-soluble insults such as bodily wastes. Thus, the compositions of the

invention improve the function of the skin barrier. Moreover, inclusion of the combination of dimethicone/alkyl silicone wax to the compositions of the invention provides a significantly better barrier to the uptake of water-soluble fluids than compositions lacking the combination.

5           The preceding test results representatively illustrate that the compositions of the present invention enhance skin barrier function when applied to the skin directly and when transferred to the skin from a liner material such as would be a component of an absorbent article.

10           While the invention has been described in detail with respect to the specific aspects thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these aspects. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.

CLAIMS

We claim:

- 5 1. An absorbent article comprising:
- (a) an outer cover;
  - (b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;
  - (c) an absorbent body that is located between the bodyside liner and the outer  
10 cover; and
  - (d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 0.1 to about 95 percent by weight of natural fats or oils, from about 0.1 to about 10 percent by weight of sterols or sterol derivatives, from about 1 to about 95 percent by weight of emollient, from about  
15 5 to about 95 percent by weight of a solidifying agent and from about 0.1 to about 25 percent by weight of a viscosity enhancer.
2. The absorbent article of claim 1, wherein the composition has a melting point from about 32°C to about 100°C.
- 20 3. The absorbent article of claim 1, wherein the composition has a viscosity of from about 10 to about 10,000 centipoise at a temperature of 60°C and has a viscosity of from about 200 to about 100,000 centipoise at 55°C.
- 25 4. The absorbent article of claim 1, wherein the composition has a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.
5. The absorbent article of claim 1, wherein the composition is on the bodyfacing surface in an amount of from about 0.1 grams per meter squared ( $\text{g/m}^2$ ) to about 30  $\text{g/m}^2$ .
- 30 6. The absorbent article of claim 1, wherein the natural fat or oil of the composition is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil,  
35 Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl

Alcohol, Myristyl Alcohol, Behenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

5 7. The absorbent article of claim 1, wherein the sterol or sterol derivative of the composition is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C<sub>10</sub>-C<sub>30</sub> cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate,  
10 ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

8. The absorbent article of claim 1, wherein the emollient of the composition is selected from petrolatum, vegetable based oils, mineral oils, dimethicone, lanolin, glycerol esters,  
15 alkoxyated carboxylic acids, alkoxyated alcohols, fatty alcohols and mixtures thereof.

9. The absorbent article of claim 1, wherein the solidifying agent of the composition is selected from beeswax, candelilla wax, carnauba wax, cerasin, microcrystalline wax, hydrogenated microcrystalline wax, alkylmethylsiloxanes, jojoba wax, lanolin wax,  
20 ozokerite, paraffin, polyethylene, C<sub>30</sub> alkyl dimethicone, cetyl esters, zinc stearate and mixtures thereof.

10. The absorbent article of claim 1, wherein the viscosity enhancer of the composition is selected from polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers,  
25 polyethylene, silica, silica silylate, silica methyl silylate, colloidal silicone dioxide, alkyl hydroxy ethyl cellulose and mixtures thereof.

11. The absorbent article of claim 1, wherein the composition further includes from about 0.5 to about 5 percent by weight of a rheology modifier.  
30

12. The absorbent article of claim 11, wherein the rheology modifier is selected from silica, silica silylate, silica methyl silylate, quaternary starch compounds and mixtures thereof.

35 13. An absorbent article comprising:  
(a) an outer cover;



- (b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;
- (c) an absorbent body that is located between the bodyside liner and the outer cover; and
- 5 (d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 0.1 to about 95 percent by weight of natural fats or oils, from about 0.1 to about 10 percent by weight of sterols or sterol derivatives, from about 1 to about 95 percent by weight of emollient, from about 5 to about 95 percent by weight of a solidifying agent, from about 0.1 to about 25 percent by
- 10 weight of a viscosity enhancer, from about 0.5 to about 30 percent by weight of a dimethicone and from about 0.5 to about 30 percent by weight of an alkyl silicone.

14. An absorbent article comprising:

- (a) an outer cover;
- 15 (b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;
- (c) an absorbent body that is located between the bodyside liner and the outer cover; and a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 5 to about 75 percent by weight of
- 20 natural fats or oils selected from avocado oil, borage oil, sunflower oil, soybean oil, corn oil, cottonseed oil and mixtures thereof; from about 0.5 to about 5 percent by weight of sterols or sterol derivatives selected from cholesterol, sitosterol, stigmasterol, tall oil sterol, soy sterol and mixtures thereof; from about 20 to about 75 percent by weight of emollient selected from petrolatum,
- 25 dimethicone, lanolin and mixtures thereof; from about 25 to about 75 percent by weight of a solidifying agent selected from cerasin, microcrystalline wax, ozokerite, alkylmethylsiloxanes and mixtures thereof; and from about 5 to about 20 percent by weight of a viscosity enhancer selected from polyolefin resins, ethylene/vinyl acetate copolymers, polyethylene, silica and mixtures thereof.

30

15. The absorbent article of claim 14, wherein the composition has a melting point from about 32°C to about 100°C.

- 16. The absorbent article of claim 14, wherein the composition has a viscosity of from
- 35 about 10 to about 10,000 centipoise at a temperature of 60°C and has a viscosity of from about 200 to about 100,000 centipoise at 55°C.

17. The absorbent article of claim 14, wherein the composition has a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.
18. The absorbent article of claim 14, wherein the composition is on the bodyfacing surface in an amount of from about 0.1 grams per meter squared ( $\text{g/m}^2$ ) to about 30  $\text{g/m}^2$ .
19. A method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article comprising the steps of:
- (a) heating a composition comprising a natural fat or oil, a sterol or sterol derivative, an emollient, a solidifying agent and a viscosity enhancer, to a temperature above the melting point of the composition, the composition having a melting point of from about 32°C to about 100°C;
  - (b) applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article; and
  - (c) resolidifying the composition.
20. The method of claim 19, wherein after the step of resolidification, the composition has a viscosity of greater than about 200 centipoise.
21. The method of claim 19, wherein after the step of resolidification, the composition has a penetration hardness of from about 5 to about 365 millimeters at 25°C.
22. The method of claim 19, wherein after the step of heating, the composition is applied by spraying.
23. The method of claim 19, wherein after the step of heating, the composition is applied by slot coating.
24. The method of claim 19, wherein after the step of heating, the composition is applied by printing.
25. A composition comprising from about 0.1 to about 95 percent by weight of natural fat or oil, from about 0.1 to about 10 percent by weight of sterols and sterol derivatives, from about 1 to about 95 percent by weight of emollient, from about 5 to about 95 percent by weight of solidifying agent, and from about 1 to about 25 percent by weight of viscosity enhancer.

26. The composition of claim 25, wherein the composition has a melting point from about 32°C. to about 100°C.
27. The composition of claim 25, wherein the composition has a viscosity greater than  
5 about 200 centipoise at 55°C.
28. The composition of claim 25, wherein the composition has a penetration hardness of from about 5 to about 365 millimeters at 25°C.
- 10 29. The composition of claim 25, wherein the natural fat or oil is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric  
15 Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Behenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.
- 20 30. The composition of claim 25, wherein the sterol and sterol derivative is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C<sub>10</sub>-C<sub>30</sub> cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate,  
25 ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.
31. The composition of claim 25, wherein the emollient is selected from petrolatum, vegetable based oils, mineral oils, dimethicone, lanolin, glycerol esters, alkoxylated  
30 carboxylic acids, alkoxylated alcohols, fatty alcohols and mixtures thereof.
32. The composition of claim 25, wherein the solidifying agent is selected from beeswax, candelilla wax, carnauba wax, cerasin, microcrystalline wax, hydrogenated microcrystalline wax, alkylmethylsiloxanes, jojoba wax, lanolin wax, ozokerite, paraffin,  
35 polyethylene, C<sub>30</sub> alkyl dimethicone, cetyl esters, zinc stearate and mixtures thereof.

33. The composition of claim 25, wherein the viscosity enhancer is selected from polyolefin resins, lipophilic/oil thickeners, ethylene/vinyl acetate copolymers, polyethylene, silica, silica silylate, silica methyl silylate, colloidal silicone dioxide, alkyl hydroxy ethyl cellulose and mixtures thereof.

5

34. The composition of claim 25, wherein the composition further comprises from about 0.5 to about 30 percent by weight of a siloxane.

10 35. The composition of claim 25, wherein the composition further comprises from about 0.5 to about 30 percent by weight of an alkyl silicone.

36. A method for enhancing skin barrier function on a skin surface of a user, comprising the steps of:

- 15 a) contacting the skin surface of the user with a bodyfacing surface of a liner material, the bodyfacing surface having a composition comprising a natural fat or oil, a sterol or sterol derivative, an emollient, a solidifying agent and a viscosity enhancer;
- 20 b) maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface; and
- c) repeating the contact of the skin surface with the bodyfacing surface of the liner material for a sufficient period of time to enhance skin barrier function, wherein the composition comprises from about 0.1 to about 95 percent by weight of natural fat or oil, from about 0.1 to about 10 percent by weight of a sterol or a sterol derivative, from about 1 to about 95 percent by weight of an emollient, from 25 about 5 to about 95 percent by weight of a solidifying agent, and from about 1 to about 25 percent by weight of a viscosity enhancer.

37. The method of claim 36, wherein the composition has a melting point from about 32°C. to about 100°C.

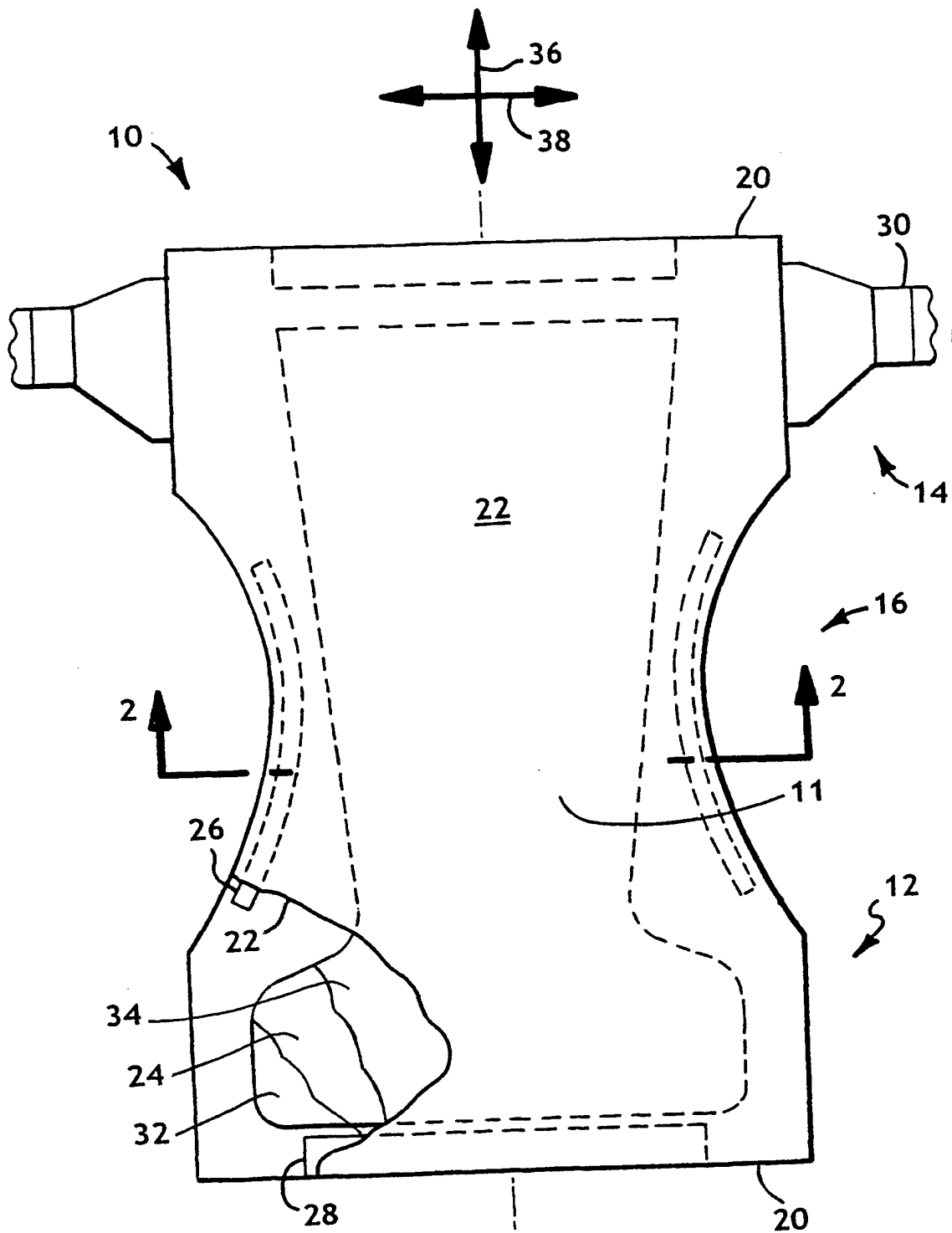
30

38. The method of claim 36, wherein the composition has a viscosity greater than about 200 centipoise at 55°C.

39. The method of claim 36, wherein the composition has a penetration hardness of from 35 about 5 to about 365 millimeters at 25°C.

40. The method of claim 36, wherein the composition further comprises from about 0.5 to about 30 percent by weight of a siloxane.

41. The method of claim 36, wherein the composition further comprises from about 0.5 to  
5 about 30 percent by weight of an alkyl silicone.



**FIG. 1**

2/4

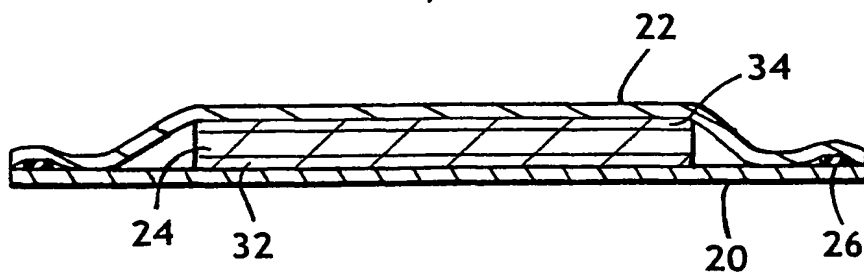


FIG. 2

3/4

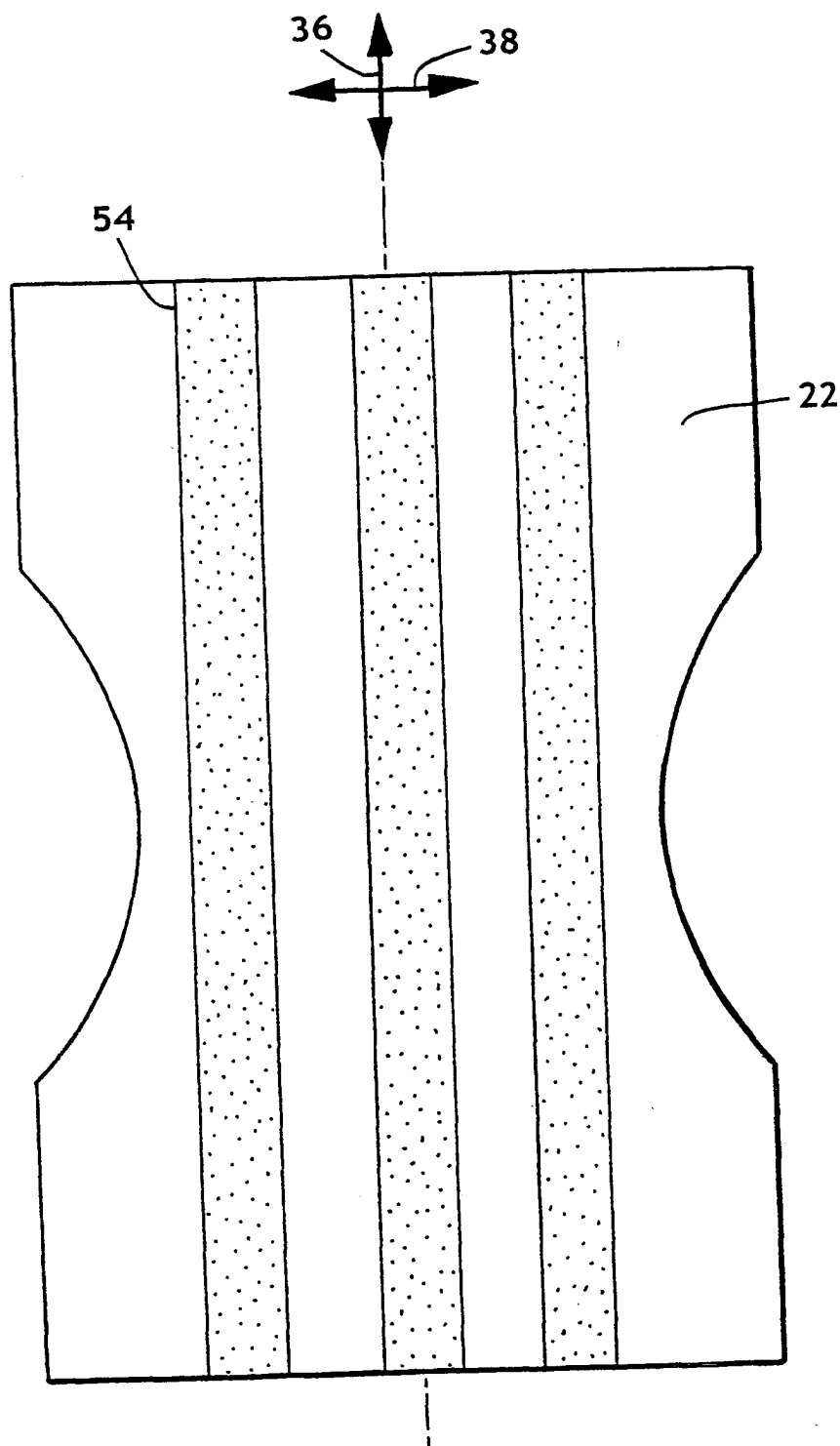


FIG. 3



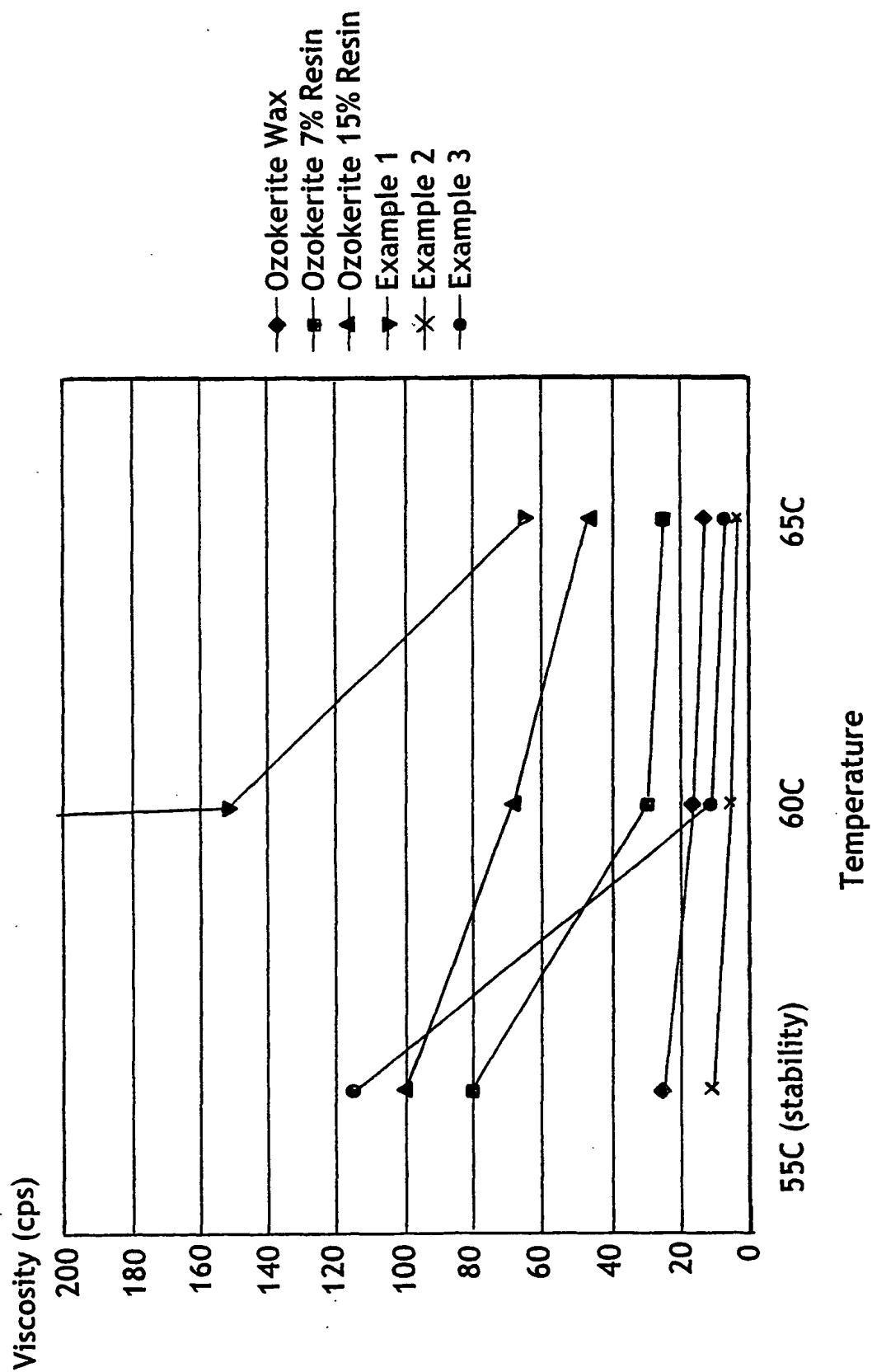


FIG. 4



(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
2 May 2002 (02.05.2002)

PCT

(10) International Publication Number  
**WO 02/034305 A3**

(51) International Patent Classification<sup>7</sup>: **A61L 15/34**,  
15/42

(21) International Application Number: PCT/US01/32013

(22) International Filing Date: 11 October 2001 (11.10.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
09/694,052 20 October 2000 (20.10.2000) US

(71) Applicant: **KIMBERLY-CLARK WORLDWIDE, INC.** [US/US]; 401 N. Lake Street, Neenah, WI 54956 (US).

(72) Inventors: **KRZYSIK, Duane, Gerard**; 1112 E. Melrose Avenue, Appleton, WI 54911 (US). **OTTS, David**,

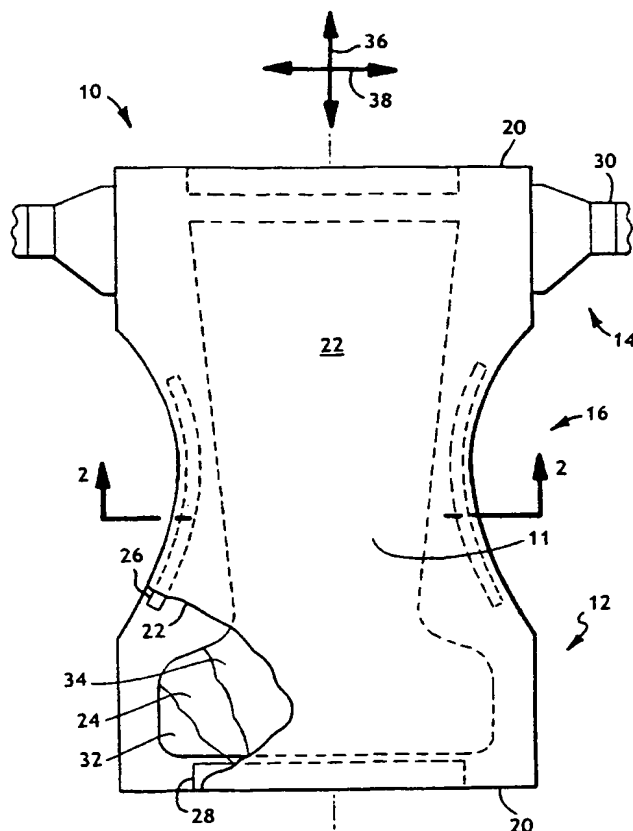
**Roland**; 809 N. Kensington Drive, Appleton, WI 54915 (US). **LANGE, Beth, Anne**; 415 S. Olde Oneida Street, #319, Appleton, WI 54911 (US). **NELSON, Brenda, Marie**; 3124 S. Huckleberry Lane, Appleton, WI 54915 (US). **BROCK, Earl, David**; 645 Highview Lane, Kimberly, WI 54136 (US). **TATE, Martha, Lillian**; 7390 Twin Branch Road, Atlanta, GA 30328 (US).

(74) Agents: **DUDKOWSKI, Alyssa, A.** et al.; Kimberly-Clark Worldwide, Inc., 401 N. Lake Street, Neenah, WI 54956 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: ABSORBENT ARTICLES ENHANCING SKIN BARRIER FUNCTION



(57) Abstract: The present invention relates to compositions and absorbent articles including compositions for protecting and enhancing the barrier function of the skin. The compositions can be applied to the bodyfacing surfaces of absorbent articles so that the compositions come into contact with the skin. The compositions of the invention have improved stability on the bodyfacing surfaces after processing. The compositions of the invention provide several benefits including prevention and alleviation of skin irritations associated with the use of absorbent articles. The compositions can include natural fats, natural oils, sterols or sterol derivatives, emollients, solidifying agents and viscosity enhancers.

WO 02/034305 A3



(84) **Designated States (regional):** ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

**Declarations under Rule 4.17:**

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW. ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL,

**Published:**

— with international search report

(88) **Date of publication of the international search report:**  
6 September 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

## INTERNATIONAL SEARCH REPORT

ational Application No  
PCT/US 01/32013A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61L15/34 A61L15/42

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61L A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 12530 A (PROCTER & GAMBLE) 18 March 1999 (1999-03-18) claims	1-24, 36-41
A	WO 99 13861 A (PROCTER & GAMBLE) 25 March 1999 (1999-03-25) claims	1-35
A	GB 880 276 A (UPJOHN CO) 18 October 1961 (1961-10-18) claims examples	25-35
A	US 5 738 859 A (POSNER ROBERT M) 14 April 1998 (1998-04-14) claims column 1, line 4 - line 28 column 2, line 7 - line 27	25-35
-/--		

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

Date of the actual completion of the international search

6 June 2002

Date of mailing of the international search report

21/06/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Muñoz, M

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/32013

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 884 688 A (WARNER LAMBERT PHARMACEUTICAL) 13 December 1961 (1961-12-13) claims ---	25-35
A	DATABASE WPI Section Ch, Week 198506 Derwent Publications Ltd., London, GB; Class D21, AN 1985-034312 XP002201388 & JP 59 227816 A (KAO CORP), 21 December 1984 (1984-12-21) abstract ---	25-35
P, X	WO 00 64503 A (KIMBERLY CLARK CO) 2 November 2000 (2000-11-02) cited in the application claims -----	1-41

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/32013

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9912530	A	18-03-1999	AU 9227398 A	29-03-1999
			BR 9814043 A	03-10-2000
			CA 2302377 A1	18-03-1999
			CN 1278720 T	03-01-2001
			EP 1011645 A1	28-06-2000
			HU 0100240 A2	28-06-2001
			JP 2001515760 T	25-09-2001
			TR 200000694 T2	21-09-2000
			WO 9912530 A1	18-03-1999
			ZA 9808307 A	11-03-1999
WO 9913861	A	25-03-1999	AU 735421 B2	05-07-2001
			AU 8745598 A	05-04-1999
			BR 9811789 A	05-09-2000
			CA 2302561 A1	25-03-1999
			CN 1277548 T	20-12-2000
			EP 1011630 A1	28-06-2000
			WO 9913861 A1	25-03-1999
			JP 2001516712 T	02-10-2001
			US 6153208 A	28-11-2000
			ZA 9808057 A	17-02-1999
GB 880276	A	18-10-1961	DE 1106455 B	10-05-1961
US 5738859	A	14-04-1998	NONE	
GB 884688	A	13-12-1961	FR 1255602 A	10-03-1961
JP 59227816	A	21-12-1984	JP 1454815 C	25-08-1988
			JP 63002531 B	19-01-1988
WO 0064503	A	02-11-2000	US 6287581 B1	11-09-2001
			AU 4491300 A	10-11-2000
			BR 0009982 A	08-01-2002
			CN 1348387 T	08-05-2002
			EP 1173232 A1	23-01-2002
			WO 0064503 A1	02-11-2000
			US 2001014350 A1	16-08-2001

**THIS PAGE BLANK (USPTO)**



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**